2 HEALTH

Health', a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, is a pre-condition to the realization of human potential and for attainment of happiness. Thus, health is both a social and an economic good. The Directive Principles of State Policy in the Constitution of India mandate 'improvement of public health' as one of the primary duties of the State. The Central and State Governments have been taking proactive steps to promote health of the people by creating a network of public healthcare facilities, which provide free medical services, and also proactively control the spread of diseases.

Health Indicators and India

- **Indicators for Maternal Health**

The Maternal Mortality Ratio (MMR) is the number of women who die from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, per 100,000 live births. The National Maternal Mortality Rate (MMR) level has come down from 327 per 100,000 live births in 1999-2001 to 212 per 100,000 live births in 2007-09, registering a decline of 35.2% over a span of eight years.

- **Indicators for Child Health**

Universal immunization of children against the 6 vaccine-preventable diseases (namely, Tuberculosis, Diphtheria, Whooping cough, Tetanus, Polio, and Measles) is crucial to reducing infant and child mortality.

The Under-Five Mortality Rate (U5MR) is the probability (expressed as a rate per 1000 live births) of a child born in a specified year dying before reaching the age of 5 if subjected to current age-specific mortality rates. According to Sample Registration System (SRS) 2010, U5MR at national level stood at 55 in 2011 compared to 59 in 2010.

The number of infant deaths in less than a year of birth per 1000 live births is referred to as Infant Mortality Rate (IMR). Data is expressed as number of deaths per 1000 live births. The country has observed a continuous decline in IMR. From 58 in 2005 it has come down to 44 in 2011 (SRS). The decline in IMR has been noticed both for male and female during the period.

IMR for infant girls has been consistently higher than IMR of infant boys in India. The IMR (Girls) has however, experienced greater decline than IMR (Boys), the decline being from 81 per 1000 live births in 1990 to 46 per 1000 live births in 2011 for infant girls and from 78 per 1000 live births in 1990 to 43 per 1000 live births in 2011 for infant boys.

The Neo-natal (less than 29 days) mortality rate was 31 in 2011 compared with 33 in 2010 at the all-India level.

- **Indicators for Hygiene**

The overall proportion of households having access to improved water sources increased from 68.2% in 1992-93 to 91.4% in 2008-09. The urban coverage increased from 87.6% to 94% and the rural coverage from 61.0% to 90.4% during the same period.

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According to Census 2001, 36.4% of the households had access to latrine which increased to 46.9% in Census 2011. The access to latrine for rural households increased from 21.9% in 2001 to 30.7% in 2011. For urban households, it increased from 73.7% to 81.4% during this period. What is important to note is that 53.1% households in India comprising 69.3% rural and 18.6% urban households did not have access to latrine as per Census 2011.

The proportion of households using improved sanitation facilities, according to NFHS-3 estimates for 2005-06 was 40.6%. This proportion was 2.3% in 2007-08 as per DLHS-3 and 47.6% in 2008-09 as per NSS Report No 535 on Housing Conditions and Amenities in India.

Public Health System of India

Primary Health care has been defined as an essential health care which should be based on practical, scientifically sound and socially acceptable methods and technology. It should be made universally accessible to the individuals and the family in the community through their full participation. It is to be made available at a cost which the community and the country can afford to maintain at every stage of its development in a spirit of self-reliance and self-determination.

Primary health care is the first level of contact of the individuals, the family and the community with the national health system bringing health care as close as possible to where the people live and work. It constitutes the first element of the process of continuing health care, and this should get full support from the rest of the health system.

This support would be required in the following areas:

(a) Consultation on health problems;

(b) Referral of patients to local or other specialized institutions;

(c) Supportive supervision and guidance;

(d) Logistic support and supplies.

Keeping in view the constitutional obligations, the Government of India has planned Primary healthcare centres. Thus based on population norms, the primary health care infrastructure has been developed in rural areas as a three-tier system Sub-Centre, Primary Health Centre and Community Health Centre; and the services of these three centres are also assisted by the presence of Rural Family Welfare Centres. The Sub-Centres provide first level contacts between the primary healthcare system and the community. Tasks assigned to these health institutions vary from state to state. In some states the Auxiliary Nurse Midwifes (ANMs) stationed in sub-centres perform deliveries and refer only the complicated cases to Primary Health Care (PHCs) or beyond. In some states the emphasis is on interpersonal communication so as to bring a behavioural change in maternal and child health, family welfare, nutrition, immunization, diarrhoeal control and control of communicable disease. The PHC is referral unit for about 5-6 Sub-Centres. Activities of PHC include curative, preventive and promotive health care as well as family welfare services. CHCs serve as First Referral Units (FRU) for 4-5 PHCs and also provide facilities for obstetric care and specialist consultations. According to norm, each Central Health Services (CHC) should have at least 30 beds, one operation theatre, X-Ray machine, labour room, laboratory facilities, and to be staffed by 4 medical specialists - Surgeon, Physician, Gynaecologist and Paediatrician.

Initiatives Taken In Health Sector

1. Mission Indradhanush

The Ministry of Health & Family Welfare has launched "Mission Indradhanush", depicting 7 colours of the rainbow, to fully immunise more than 89 lakh children who are either unvaccinated or partially vaccinated;

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those that have not been covered during the rounds of routine immunisation for various reasons. They will be fully immunised against 7 life-threatening but vaccine preventable diseases which include diphtheria, whooping cough, tetanus, polio, tuberculosis, measles and hepatitis-B. In addition, vaccination against Japanese Encephalitis and Haemophilus influenza type-B will be provided in selected districts/states of the country. Pregnant women will also be immunised against tetanus.

In a bid to protect the children from more vaccine preventable diseases, new vaccines are proposed to be introduced as part of India's Universal Immunisation Programme (UIP). Introduction of these vaccines will be done in a phased manner over a period of time, depending upon the field level assessments and preparedness. In addition, it has been decided to introduce an adult vaccine against Japanese Encephalitis (JE) in the high burden districts.

The new vaccines are:

a. Inactivated Polio Vaccine (IPV)

India is Polio free but to maintain this status, the Inactivated Polio Vaccine was introduced on 30th October 2015. The vaccine has been initially introduced in 6 states: Bihar, Uttar Pradesh, Madhya Pradesh, Gujarat, Assam and Punjab. This will benefit 2.7 crore children every year.

b. Adult Japanese Encephalitis (JE) Vaccine

21 high burden districts have been identified in Assam, Uttar Pradesh and West Bengal for adult JE vaccination in the age-group of 15-65 years. This will cut down deaths and morbidity due to Japanese Encephalitis in adults as well.

c. Rotavirus Vaccine

Rotavirus is the leading cause of severe diarrhoea among infants and young children in the world. Each year India loses approximately 2 lakh children to diarrhoea out of which 1 lakh deaths are caused by Rotavirus. Rotavirus vaccine implemented to full scale would save approximately 1 lakh lives every year. The vaccine is planned to be introduced in first quarter of 2016 in 4 states initially i.e. Odisha, Himachal Pradesh, Haryana and Andhra Pradesh.

d. Measles Rubella (MR) Vaccine

Measles Rubella vaccine eliminates measles and controls Rubella in the country. The vaccine will help to reduce incidence of Congenital Rubella Syndrome. As on date, approximately 25,000 cases of Congenital Rubella Syndrome (CRS) are estimated each year and if the child survives, this adds to the disabilities in the country. MR vaccination campaign will be carried out after appropriate planning and will cover 45 crore children.

2. Special New born Care Units (SNCUs)

In order to strengthen the care of sick, premature and low birth weight newborn Special New born Care Units (SCNU) have been established at District Hospitals and tertiary care hospitals. These are 12-20 bedded units, with 4 trained doctors and 10-12 nurses and support staff with provision of 24x7 services to sick newborns.

Ministry of Health & Family Welfare (MoHFW) provides free entitlement of care at these centres under Janani Shishu Suraksha Karyakaram. Each SNCU is expected to provide: Care at birth including resuscitation of asphyxiated newborn, sick newborn and routine postnatal care. Follow up of high risk newborn and Immunization/Referral Services are also provided for. Once the baby is discharged to home ASHA (Accredited Social Health Activist) will do the follow up of these babies for one year. District Early Intervention Centre

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(DEIC) have also been linked with SNCU to provide specialized care to the babies with special needs and delays.

3. Daksh

For improving the skills of healthcare providers and to enhance their capacity to provide quality (Reproductive, Maternal, Neonatal, Child & Adolescent Health) RMNCH+A services, Government of India has established 5 National Skills lab "Daksh" at Delhi and in NCR region with support from Maternal health division, Government of India and Liverpool School of Tropical Medicine (LSTM).

The objectives of Skills lab are to :

a) Facilitate acquisition/ reinforcement of key standardized technical skills and knowledge by service providers for RMNCH+A services

b) Ensures the availability of skilled personnel at health facilities

c) Improves the quality of pre-service training

d) Provides continuing Nursing education/ Continuing medical education.

The target audience of 6 days skills lab training are Obstetricians and Gynaecologists, Paediatricians, Medical Officers, staff Nurses, Auxiliary Nurse Midwife (ANM), state trainers and faculty of Nursing School/ colleges and Medical College who can adapt it for strengthening pre-service teaching.

4. Family Planning

Three new choices are now being introduced in the National Family Planning program.

a) Injectable Depot Medroxy Progesterone Acetate: The Drugs Technical Advisory Board (DTAB) agreed to the introduction of the injectable contraceptive DMPA in the public health system under the National Family Planning Programme.

b) Proqestine-only Pills (POP): Progesterone only pill for the lactating mothers.

c) Centchroman: A non-hormonal once a week pill.

5. Rashtriya Kishor Swasthya Karyakram (RKSK)

The Rashtriya Kishor Swasthya Karyakram (RKSK) was launched with an overarching aim to address sexual and reproductive health, nutrition, injuries and violence (including gender based violence), prevention of non-communicable diseases, mental health and substance misuse related concerns of 253 million adolescents of our country through effective and coherent implementation of programmes and schemes. The short term goal is to ensure holistic health and development of adolescents and the long term outcome will be increased social and economic productivity of our nation.

The programme is underpinned by the principles of equity and inclusion; rights based approach, adolescent and community participation and strategic partnership. The key components of the program are community based interventions; facility based interventions; social and behavior change communication; and inter-sectoral convergence.

6. The National Health Mission (NHM)

The National Health Mission (NHM) encompasses its two Sub-Missions, the National Rural Health Mission (NRHM) and the National Urban Health Mission (NUHM). The main programmatic components include Health System Strengthening in rural and urban areas, Reproductive-Maternal- Neonatal-Child and Adolescent

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Health (RMNCH+A), and Communicable and Non-Communicable Diseases. The NHM envisages achievement of universal access to equitable, affordable & quality health care services that are accountable and responsive to people's needs.

National Rural Health Mission (NRHM): NRHM seeks to provide accessible, affordable and quality health care to the rural population, especially the vulnerable groups. Under the NRHM, the Empowered Action Group (EAG) States as well as North-eastern States, Jammu and Kashmir and Himachal Pradesh have been given special focus. The thrust of the mission is on establishing a fully functional, community owned, decentralized health delivery system with inter-sectoral convergence at all levels, to ensure simultaneous action on a wide range of determinants of health such as water, sanitation, education, nutrition, social and gender equality.

National Urban Health Mission (NUHM): NUHM seeks to improve the health status of the urban population particularly urban poor and other vulnerable sections by facilitating their access to quality primary health care. NUHM covers all state capitals, district headquarters and other cities/towns with a population of 50,000 and above (as per census 2011) in a phased manner. Cities and towns with population below 50,000 will continue be covered under NRHM.

- **Key Initiatives Under NHM:**

a) **Launch of National Quality Assurance Framework for Health facilities:** To improve quality of health care in over 31000 public facilities and provide a clear roadmap to states, Quality Standards for District Hospitals (DHs), Community Health Centres (CHCs) and Primary Health Care PHCs under National Quality Assurance Framework.

b) **Launch of Kayakalp- An initiative for Award to Public Health Facilities:** Kayakalp- initiative has been launched to promote cleanliness, hygiene and infection control practices in public health facilities. Under this initiative public healthcare facilities shall be appraised and such public healthcare facilities that show exemplary performance meeting standards of protocols of cleanliness, hygiene and infection control will receive awards and commendation. Further, Swachhta Guidelines for public health facilities to promote Cleanliness, Hygiene and Infection Control Practices in public health facilities. The Guidelines provide details on the planning, frequency, methods, monitoring etc. with regard to Swachhta in public health facilities.

c) **Launch of National Family Health Survey (NFHS)-IV**: NFHS-IV was launched in mid-2014 to provide essential data and information on important emerging health and family welfare elements to track progress on key parameters and provide evidence for policy and programme. The field work of NFHS-IV is under progress. This survey results are expected in 2016 and will provide national, state and district level data.

d) **Launch of India Newborn Action Plan (INAP):** Currently, there are estimated 7.47 lakh neonatal deaths annually. In September 2014, INAP was launched for accelerating the reduction of preventable newborn deaths and stillbirths in the country. With the goal of attaining 'Single Digit Neo-natal Mortality Rate (NMR) by 2030' and 'Single Digit Still Birth Rate (SBR) by 2030'. The neo-natal deaths are expected to reduce to below 2.28 lakh annually by 2030, once the goal is achieved.

e) **Free Drugs Service Initiative:** An incentive of up to 5% additional funding (over and above the normal allocation of the state) under the NHM is provided to those States that introduce free medicines scheme. Under the NHM-Free Drug Service Initiative, substantial funding is available to States for provision of free drugs subject to States/UTs meeting certain specified conditions. Detailed Operational Guidelines for NHM- Free Drugs Service Initiative have also been released to the States.

f) **Kilkari& Mobile Academy:** To create proper awareness among pregnant women, parents of children and field workers about the importance of Anti Natal Care (ANC), institutional delivery, Post-Natal Care (PNC) and immunization, it was decided to implement the Kilkari and Mobile Academy services in Pan

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India in phased manner. In the first phase Kilkari would be launched in 6 states viz. Uttrakhand, Jharkhand, Uttar Pradesh, Odisha, Rajasthan (HPDs) & Madhya Pradesh (HPDs). The Mobile Academy would be launched in 4 states viz. Uttrakhand, Jharkhand, Rajasthan & Madhya Pradesh.

Shortcomings of the Healthcare Sector

The system suffers from the following weaknesses:

- **Availability of healthcare services:**

From the public and private sectors taken together is quantitatively inadequate. This is starkly evident from the data on doctors or nurses per lakh of the population. At the start of the 11th Plan, the number of doctors per lakh of population was only 45, whereas, the desirable number is 85 per lakh population. Similarly, the number of Nurses and Auxiliary Nurse and Midwifes (ANMs) available was only 75 per lakh population whereas the desirable number is 225. The overall shortage is exacerbated by a wide geographical variation in availability across the country. Rural areas are especially poorly served.

- **Quality of healthcare services**

It varies considerably in both the public and private sector. Many practitioners in the private sector are actually not qualified doctors. Regulatory standards for public and private hospitals are not adequately defined and, in any case, are ineffectively enforced.

- **Affordability of healthcare:**

It is a serious problem for the vast majority of the population, especially in tertiary care. The lack of extensive and adequately funded public health services pushes large numbers of people to incur heavy out of pocket expenditures on services purchased from the private sector. Out of pocket expenditures arise even in public sector hospitals, since lack of medicines means that patients have to buy them. This results in a very high financial burden on families in case of severe illness. A large fraction of the out of pocket expenditure arises from outpatient care and purchase of medicines, which are mostly not covered even by the existing insurance schemes. In any case, the percentage of population covered by health insurance is small.

- **Poor Rural Healthcare Infrastructure**

Mahatma Gandhi had a dream that India would be a land of self-sustaining villages. The true India is to be found not in its few cities, but in its 700,000 villages. If the villages perish, India will perish too." The health scenario in rural India would've caused him great pain. The basic problem in this case is the lack of resources - human or otherwise. Initiatives like the National Rural Health Mission (NRHM) haven't made much headway.

Here are some of the stark facts about the lives of our rural brethren:

a) 50% of all villagers have no access to healthcare providers.

b) 37% are chronically starved.

c) 10% of all babies die before their first birthday.

d) 50% of all babies are likely to be permanently stunted due to lack of proper nutrition.

e) 33% people have no access to toilets, while 50% defecate in the open.

- **Women's and Children's Health**

According to a poll by Thomson Reuters, India is the worst place for women among G20 nations. Female foeticide, unequal rights, dowry killings, poor maternal health and lack of sexual education are just some of the reasons for the same.

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Here are few facts about women health in India:

a) 12 million girls were aborted in the last 3 decades in India.

b) Child marriage has a domino effect since this also leads to lowered education levels and lower levels of awareness.

c) 45% Indian women are married before they turn 18. This results in early pregnancies, higher morbidity and mortality rates.

d) A mother dies every 10 minutes in India.

The children's healthcare situation is equally bad. While some diseases have been controlled to a large extent others continue to wreak havoc.

a) Over 1.25 million children die annually in India.

b) 48% of all children have stunted growth due to malnutrition.

c) Only 7% children in India receive the minimum acceptable diet set by the WHO. The other countries we share such a dubious honour with are sub-Saharan African countries and Pakistan.

- Low government spending, high out-of-pocket expenses and lack of insurance.

As we mentioned before, the government spending on healthcare is grossly inadequate. It spends about 1% of the nation's GDP on healthcare. This has led to very high Out-Of-Pocket (OOP) expenditure for the general public. This means that 78% of all spends on healthcare are paid by the people and 72% of this is on drugs alone. Estimates suggest that 39 million people are forced into poverty because of medical expenditure.

- **Rise of Lifestyle diseases**

While rural India battles 3rd world diseases like Malaria and Dengue, rising urbanisation has led to the middle and upper classes being afflicted with 'developed world' lifestyle diseases like Diabetes and Obesity. A fast food culture, increased smoking and alcohol consumption has led to a rise in Obesity related diseases like Diabetes and Cardiovascular ailments.

- **Medical Education and Healthcare Human Resources**

India has some top quality medical institutes which provide quality education and a huge number of medical professionals are added to the task-force every year. While that is indeed a huge number, most of them are based in urban centres resulting in deficit of healthcare services in rural and semi-urban India.

Some facts are:

a) Urban India has 4 times more doctors and 3 times more nurses than rural India.

b) Only 193 of India's 640 districts have medical colleges. This has a domino effect on the local community with doctors moving away, either to urban centres with medical colleges or abroad.

c) Almost 80% of the medical colleges are located in South and West India creating a dearth of professionals in Central, Eastern and Northern India.

- **High number of avoidable deaths**

Avoidable deaths refer to those that could've been avoided extremely easy with either the most basic or cheap medication or treatment. Some of the more common avoidable diseases are malaria, tuberculosis, kalaazar and

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Japanese Encephalitis. Deaths from conditions like nutritional deficiencies or perinatal deaths are also considered in this list. A rough estimate suggests that over 2.1 million people died in India from conditions that could've been avoided.

12th Five Year Plan Recommendations to Improve Health

National Health Outcome Goals for the 12th Plan:

The health system for the 12th Plan will address the following objectives.

- Reduction of Maternal Mortality Ratio (MMR): At historical rate of decline, India is projected to have an MMR of 149 by 2015 and 127 by 2017. An achievement of the Millennium Development Goal (MDG) of reducing MMR to 109 by 2015 would require a further acceleration of this historical rate of decline. At this accelerated rate of decline, the country can achieve an MMR of 75 by 2017.
- Reduction of Infant Mortality Rate (IMR): At historical rate of decline, India is projected to have an IMR of 38 by 2015 and 34 by 2017. An achievement of the MDG of reducing IMR to 27 by 2015 would require an even further acceleration of this historical rate of decline. If this accelerated rate is sustained, the country can achieve an IMR of 19 by 2017.
- Reduction of Total Fertility Rate (TFR): India is on track for the achievement of a TFR target of 2.1 by 2017, which is necessary to achieve net replacement level of unity, and realize the long cherished goal of the National Health Policy, 1983 and National Population Policy of 2000. Stagnant TFR over the last two years is, however, a matter of concern.
- Prevention and reduction of underweight children under 3 years: Underweight children are at an increased risk of mortality and morbidity. At the current rate of decline, the prevalence of underweight children is expected to be 29% by 2015, and 27% by 2017. An achievement of the MDG of reducing undernourished children under 3 years to 26% by 2015 would require an acceleration of this historical rate of decline. If this accelerated rate is sustained, the country can achieve an under 3 child under-nutrition level of 23% by 2017. This particular health outcome has a very direct bearing on the broader commitment to security of life, as do MMR, IMR, Anaemia and Child sex ratio.
- Prevention and reduction of anemia among women aged 15-49 years: Anemia, the underlying determinant of maternal mortality and low birth weight, is preventable and treatable by a very simple intervention. The prevalence of anemia has shown a rising trend (58.8% in 2007, DLHS), which needs to be reversed and steeply reduced to 28%, which is half the current levels, by the end of the 12th Plan.
- Raising child sex ratio in the 0-6 year age group from 914 to 935: Like anemia, child sex ratio is another important indicator which has been showing a deteriorating trend, and needs to be targeted for priority attention.
- Prevention and reduction of burden of diseases - Communicable, Non- Communicable (including mental illnesses) and injuries: These add to the burden of disease, reduce longevity, add to health expenditure and are very amenable to public health and preventive measures. Targets for each of these conditions can be set by the Ministry of Health and Family Welfare (MoHFW) as robust systems are put in place to measure their burden.
- Reduction of households' out-of-pocket expenditure from 71% to 50% of total healthcare expenditure: Out-of-pocket expenditure on healthcare is a burden on families, particularly the poor ones, and a regressive system of financing. These need to be lowered to tolerable levels in the 12th Plan.

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New/Proposed Initiatives

1. Longitudinal Ageing Study in India

The Ministry of Health & Family Welfare launched the Longitudinal Ageing Study in India (LASI). It will survey more than 60,000 elderly over 25 years plan. The importance of the study derives from the increasing portion of elderly population in the country. The study will provide valuable data on their health needs, and issues faced by them given the changing social structures, and help us to draw policy tools to address their issues.

LASI is jointly funded by the Union Ministry of Health and Family Welfare, the United States' National Institute on Ageing, and the United Nations Population Fund-India.

Population ageing is taking place in nearly all the countries of the world. The global share of older people aged 60 years or over increased from 9.2% in 1990 to 11.7% in 2013 and will continue to grow as a proportion of the world population, reaching 21.1% by 2050. Presently, about 2/3rd of the world's older persons live in developing countries. By 2050, nearly 8 in 10 of the world's older population will live in the less developed regions.

2. Swavlamban Health Insurance Scheme

The Trust Fund for Empowerment of Persons with Disabilities, under the Department of Empowerment of People with Disabilities, Ministry of Social Justice and Empowerment, signed a Memorandum of Understanding (MoU) with the The New India Assurance Company Limited on providing a comprehensive and affordable Health Insurance Scheme - "Swavlamban Health Insurance Scheme" - for the Persons with Disabilities (PwDs).

The scheme has been designed to deliver comprehensive cover to the beneficiary as well as his family (PwD, Spouse & up to two children), has a single premium across age band and can be availed by PwDs aged between 18 years and 65 years with family annual income of less than Rs. 3,00,000 per annum. The scheme also ensures coverage of any pre-existing condition and a health Insurance cover up to Rs. 2,00,000 per annum as family floater.

NFHS-4 Data

The results from NFHS-4 in 15 States/Union Territories indicate that fewer children are dying in infancy and early childhood. After the last round of National Family Health Survey in 2005-06, infant mortality has declined in all first phase States/Union Territories for which trend data are available. All 15 States/ Union Territories have rates below 51 deaths per 1,000 live births, although there is considerable variation among the States/Union Territories. Infant mortality rates range from a low of 10 in Andaman and Nicobar Islands to a high of 51 deaths per 1000 live births in Madhya Pradesh.

Better care for women during pregnancy and childbirth contributes to reduction of maternal deaths and improved child survival. Almost all mothers have received antenatal care for their most recent pregnancy and increasing numbers of women are receiving the recommended 4 or more visits by the service providers. More and more women now give birth in health care facilities and rates have more than doubled in some States in the last decade. More than 9 in 10 recent births took place in health care facilities in Andaman and Nicobar Islands, Andhra Pradesh, Goa, Karnataka, Puducherry, Sikkim, Tamil Nadu, and Telangana, providing safer environments for mothers and new-borns.

Overall, women in the First Phase States/Union Territories are having fewer children. The total fertility rates, or the average number of children per woman, range from 1.2 in Sikkim to 3.4 in Bihar. All First Phase States/Union Territories except Bihar, Madhya Pradesh and Meghalaya have either achieved or maintained replacement level of fertility– a major achievement in the past decade.

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Full immunization coverage among children age 12-23 months varies widely in the First Phase States/Union Territories. At least 6 out of 10 children have received full immunization in 12 of the 15 States / Union Territories. In Goa, West Bengal, Sikkim, and Puducherry more than 4/5th of the children have been fully immunised. Since the last round of National Family Health Survey, the coverage of full immunization among children has increased substantially in the States of Bihar, Madhya Pradesh, Goa, Sikkim, West Bengal and Meghalaya.

Married women are less likely to be using modern family planning in 8 of the First Phase States/Union Territories. There has been any increase in the use of modern family planning methods only in the States of Meghalaya, Haryana, and West Bengal. The decline is highest in Goa followed by Karnataka and Tamil Nadu. Despite the decline, about half or more married women are using modern family planning in 8 of the 15 States/Union Territories.

Poor nutrition is less common than reported in the last round of National Family Health Survey. Fewer children under 5 years of age are now found to be stunted, showing intake of improved nutrition. In 9 States/Union Territories, less than 1/3rd of children are found too short for their age. While this reveals a distinct improvement since the previous survey, it is found that in Bihar, Madhya Pradesh and Meghalaya more than 40% of children are stunted. Wasting is still very high by international standards in all of the States/Union Territories. Anaemia has also declined, but still remains widespread. More than half of children are anaemic in 10 of the 15 States/Union Territories. Similarly, more than half of women are anaemic in 11 States/Union Territories. Over-nutrition continues to be a health issue for adults. At least 3 in 10 women are overweight or obese in Andaman and Nicobar Islands, Andhra Pradesh, Goa, Puducherry, and Tamil Nadu.

Indian families in the First Phase households are now more inclined to use improved water and sanitation facilities. Over 2/3rd of households in every State/Union Territory have access to an improved source of drinking water, and more than 90% of households have access to an improved source of drinking water in 9 of the 15 States/Union Territories. More than 50% of households have access to improved sanitation facilities in all First Phase States/Union Territories except Bihar and Madhya Pradesh. Use of clean cooking fuel, which reduces the risk of respiratory illness and pollution, varies widely among the First Phase States/ Union Territories, ranging from only about 18% of households in Bihar to more than 70% of households in Tamil Nadu and more than 80% of households in Puducherry and Goa.

Health: Issues and Regulatory Institutions

Health should be viewed as not merely the absence of disease but as a state of complete physical, mental and social well-being. The determinants of good health are: access to various types of health services and an individual's lifestyle choices, personal, family and social relationships. At present, India's health care system consists of a mix of public and private sector providers of health services. Networks of health care facilities at the primary, secondary and tertiary level, run mainly by State Governments, provide free or very low cost medical services. There is also an extensive private health care sector, covering the entire spectrum from individual doctors and their clinics, to general hospitals and super speciality hospitals.

Hereby, we are discussing the contemporary issues related to Health in India.

Food Safety - A Global Perspective

Adequate, safe and wholesome food is a vital element for the achievement of acceptable standards of living. There is increasingly worldwide concern about food safety and animal and plant health. The WTO Agreement on Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health regulations. It applies to all such measures which may, directly or indirectly, affect international trade. All

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countries have the right to adopt or enforce necessary measures to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail.

The major objectives of the work of Codex Alimentarius Commission [CAC] are to protect the health of the consumers and ensure fair practices in the food trade as well as to facilitate international trade in food. The National Codex Contact Point (NCCP) in the Ministry of Health and Family Welfare acts as the liaison office to coordinate with the other concerned government departments (at central and state level), food industry, consumers, traders, research and development institutions to ensure fulfill this objective. Article 7 of the Agreement requires the members to provide information on Sanitary or Phytosanitary requirements in the country. For this purpose each Member is required to ensure that one Enquiry Point exists which is responsible for answering all reasonable questions from interested Members as well as to provide relevant documents relating to SPS Regulations adopted or proposed, etc.

Codex Alimentarius Commission (CAC)

The Codex Alimentarius Commission was created in 1963 by Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purpose of this Programme is to protect the health of consumers, ensure fair practices in the food trade, and promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. These standards are accepted by World Trade Organization (WTO) in settling disputes in international trade.

Codex Alimentarius is a collection of standards, codes of practice, guidelines and other recommendations. The Codex General Principles of Food Hygiene introduces the use of the Hazard Analysis and Critical Control Point (HACCP), being the prime food safety management system. Several significant issues, vital to fulfilling the objectives of the Codex Alimentarius Commission, namely, protecting the health of consumers, ensuring food safety and promoting fair global trade practices are under discussion across several Codex Committees that focus on Food Safety Objectives.

Standards, codes of practice, guidelines and other recommendations:

Codex Standards - It usually relates to product characteristics and may deal with all government-regulated characteristics appropriate to the commodity, or only one characteristic. Maximum residue limits (MRLs) for residues of pesticides or veterinary drugs in foods are examples of standards dealing with only one characteristic. There are Codex general standards for food additives and contaminants and toxins in foods that contain both general and commodity- specific provisions. The Codex General Standard for the Labelling of Prepackaged Foods covers all foods in this category. Because standards relate to product characteristics, they can be applied wherever the products are traded.

Codex methods of analysis and sampling, including those for contaminants and residues of pesticides and veterinary drugs in foods, are also considered Codex standards.

Codex Codes of Practice - It includes codes of hygienic practice - define the production, processing, manufacturing, transport and storage practices for individual foods or groups of foods that are considered essential to ensure the safety and suitability of food for consumption. For food hygiene, the basic text is the Codex General Principles of Food Hygiene, which introduces the use of the Hazard Analysis and Critical Control Point (HACCP) food safety management system.

Codex Guidelines: They fall into two categories:

- Principles that set out policy in certain key areas; and

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- Guidelines for the interpretation of these principles or for the interpretation of the provisions of the Codex general standards.

Interpretative Codex guidelines include those for food labelling, especially the regulation of claims made on the label. This group includes guidelines for nutrition and health claims; conditions for production, marketing and labelling of organic foods; and foods claimed to be "halal".

Commodity Standards: By far the largest number of specific standards in the Codex Alimentarius is the group called – commodity standards.

The major commodities included in the Codex are:

- cereals, pulses (legumes) and derived products including vegetable proteins
- fats and oils and related products
- fish and fishery products
- fresh fruits and vegetables
- processed and quick-frozen fruits and vegetables
- fruit juices
- meat and meat products; soups and broths
- milk and milk products
- sugars, cocoa products and chocolate and other miscellaneous products

The Codex Alimentarius Commission's (CAC) operations:

Compiling the Codex Alimentarius: One of the principal purpose of the Commission is the preparation of food standards and their publication in the Codex Alimentarius.

The legal base for the Commission's operations and the procedures it is required to follow are published in the Procedural Manual of the Codex Alimentarius Commission. Like all other aspects of the Commission's work, the procedures for preparing standards are well defined, open and transparent.

In essence they involve:

- The submission of a proposal for a standard to be developed by a national government or a subsidiary committee of the Commission. This is usually followed by a discussion paper that outlines what the proposed standard is expected to achieve, and then a project proposal that indicates the time frame for the work and its relative priority.
- A decision by the Commission or the Executive Committee that a standard be developed as proposed. – Criteria for the Establishment of Work Priorities exist to assist the Commission or Executive Committee in their decision-making and in selecting the subsidiary body to be responsible for steering the standard through its development. If necessary, a new subsidiary body - usually a specialized task force - may be created.
- The preparation of a proposed draft standard is arranged by the Commission Secretariat and circulated to member governments for comment.

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- Comments are considered by the subsidiary body that has been allocated responsibility for the development of the proposed draft standard, and this subsidiary body may present the text to the Commission as a draft standard. The draft may also be referred to the Codex Committees responsible for labelling, hygiene, additives, contaminants or methods of analysis for endorsement of any special advice in these areas.
- Most standards take a number of years to develop. Once adopted by the Commission, a Codex standard is added to the Codex Alimentarius.

Revising and adapting-keeping the Codex Alimentarius up to date:

The Commission and its subsidiary bodies are committed to keeping the Codex standards and related texts up to date to ensure that they are consistent with current scientific knowledge and with the needs of the member countries. The procedure for revision or consolidation follows that used for the initial preparation of standards.

Codex India

"Codex India" the National Codex Contact Point (NCCP) for India, is located at the Directorate General of Health Services, Ministry of Health and Family Welfare (MOH&FW), Government of India. It coordinates and promotes Codex activities in India in association with the National Codex Committee and facilitates India's input to the work of Codex through an established consultation process.

Role of Ministry of Health & Family Welfare/Directorate General of Health Services (Codex Contact Point) now Food Safety and Standards Authority of India (FSSAI):

Food Legislation and food control infrastructure should be sufficiently developed in the country to enable provide adequate health protection and in the well being of its citizens. It should be ensured that all types of food are free from any hazards responsible for adverse health effects. The Food is also a vital and critical item of international trade. We know that the observance of food hygiene principles is a condition of utmost importance. ?Food hygiene' comprises conditions and measures necessary for the production, processing, storage and distribution of food, designed to ensure a safe, sound, wholesome product fit for human consumption. This can be achieved by evolving a Food System' regulated by competent Food Laws. In India, Prevention of Food Adulteration Act, 1954 (PFA Act) is the relevant Act. It is governed by the Ministry of Health & Family Welfare, Government. of India. This Ministry is responsible for framing or amending the laws and providing guidelines to the State Governments/Local Bodies for implementation of Rules/provisions contained under this Act. PFA Act is the statutory Act under which the quality and safety of food at the national level is regulated.

As per the provisions of the Act, Central Government has constituted a Committee called the Central Committee for Food Standards (CCFS). The CCFS is assisted by various Sub Committees. This Committee reviews the standards of food articles to regulate their manufacture, processing, storage, distribution, sale and import on regular basis. This Committee also undertakes to promote co-ordination of work on food standards being carried out by international governmental and non-governmental organizations. It has been well realized that the prime duty of this Committee is to help and guide the Central Government to promote consistency between international technical standards and domestic food standards, so as to keep the country in pace with international activities. This exercise greatly helps the country, in playing a constructive and beneficial role in international trade.

The National Codex Contact Point (NCCP) for India is located at the Directorate General of Health Services, Ministry of Health and Family Welfare (MOH&FW). It coordinates and promotes Codex activities in India in association with the National Codex Committee and various Shadow Committees and facilitates India's input to the work of Codex through an established consultation process.

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The Directorate General of Health Services, Ministry of Health and Family Welfare (MOH&FW) has been designated as the nodal Ministry for liaison with the Codex Alimentarius Commission [CAC].

National Codex Contact Point [NCCP]

The National Codex Contact Point (NCCP) acts as the liaison office to coordinate with the other concerned government departments (at central and state level), food industry, consumers, traders, research and development Institutions and academia. National Codex Committee and its Shadow Committees are to ensure that the government is backed with an appropriate balance of policy and technical advice upon which to base decisions relating to issues raised in the context of the Codex Alimentarius Commission and its subsidiary bodies.

Core Functions of NCCP-India:

The NCCP has to perform the following core functions, established by the Codex Alimentarius Commission for National Codex Contact Points :

- Act as a link between the Codex Secretariat and India Member Body;
- Coordinate all relevant Codex activities within India ;
- Receive all Codex final texts (standards, codes of practice, guidelines and other advisory texts) and • Send comments on Codex documents or proposals to the CAC or its subsidiary bodies and /or the Codex Secretariat within the time frame;
- Work in close cooperation with the National Codex Committee and its Shadow Committees;
- Act as a channel for the exchange of information and coordination of activities with other Codex Members;
- Receive invitations to Codex Sessions and inform the relevant chairpersons and the Codex Secretariat of the names of participants representing India;
- Maintain a library of Codex final texts ; and
- Promote Codex Activities throughout India.

National Codex Committee of India

The Department of Health in Ministry of Health and Family Welfare has constituted the National Codex (Food Products Standards) Committee (NCC) for liaison with the Codex Alimentarius Commission.

According to the Government of India Resolution issued by the Ministry of Health and Family Welfare, the National Codex (Food Products Standards) Committee shall meet as and when necessary to consider the various issues that may be discussed at the annual meetings of the Codex Alimentarius Commission and prepare necessary material thereof. The work of the Committee includes- standards for all the principal foods whether processed, semi-processed or raw for the distribution to the consumer. It also includes provisions in respect of food hygiene, food additives, pesticide residues, contaminants, labeling and preservation, methods of analysis and sampling, etc.

Functions of NCC- India:

- To cooperate with the Joint FAO/WHO Food Standards Programme and to nominate delegates to attend Codex meetings;
- To formulate national position in consultation with the members of NCC in the matters of Codex;

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- To study Codex documents, collect and revise all relevant information relating to technology, economics, health and control system, so as to give supporting reasons to the government in the acceptance of Codex Standards or otherwise;
- To identify organizations to take action for generation of data base or preparation of base paper projecting the country's interest for interacting with the CAC; and
- To cooperate with other local/regional or foreign organizations dealing with activities relating to food standardization.

Shadow Committees of NCC-India

The NCC has been authorized to appoint Shadow Committees (sub-committees) on subject matters corresponding to the Codex subcommittees to assist the NCC in the study or consideration of technical matters.

Officers in the rank of Joint Secretary in the concerned Department/Ministry who handle the subject at the policy level and also serve as the members of the NCC are nominated as the Chairpersons of these Shadow Committees. Specialized experts in the relevant field are nominated as members of these Shadow committees. These list of experts are reviewed from time to time to ensure that they meet the ongoing requirements of India.

Currently, the Shadow Committees assist the National Codex Committee in the following areas:

- Codex Commission
- Regional Coordinating Committee for Asia
- General Principles
- Food labelling
- Methods of Analysis and Sampling
- Pesticides Residues
- Food Hygiene
- Food Additives and Contaminants
- Food Export and Import and Certification Systems
- Special Dietary Uses
- Fish and Fishery Products
- Oils and Fats
- Fresh Fruits and Vegetables
- Processed Fruits and Vegetables
- Milk and Milk Products
- Cocoa Products and Chocolate
- Mineral Water
- Genetically Modified Food

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Functions of Shadow Committees:

- To study Codex documents, collect and revise all relevant information relating to technology, economics, health and control system so as to give supporting reasons to the government in the acceptance of Codex Standards or otherwise;
- To formulate national position in consultation with the members of the Shadow Committee with respect to the agenda for the forthcoming meeting of the Subsidiary Body and transmit them same through the NCCP;
- To formalize the delegation for the meeting in consultation with the NCCP and transmit the names to the host secretariat through the NCCP; and
- To recommend to the NCC regarding the position to be taken during the Sessions of the Commission with respect to agenda items relevant to the terms of reference of the Shadow Committees.

The Food Safety and Standards Authority of India (FSSAI)

It has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of FSSAI. The Chairperson and Chief Executive Officer of Food Safety and Standards Authority of India (FSSAI) have already been appointed by Government of India. The Chairperson is in the rank of Secretary to Government of India.

Highlights of the Food Safety and Standard Act, 2006

Various central Acts like Prevention of Food Adulteration Act, 1954 , Fruit Products Order , 1955, Meat Food Products Order , 1973,

Vegetable Oil Products (Control) Order, 194,Edible Oils Packaging (Regulation)Order 1988, Solvent Extracted Oil, De- Oiled Meal and Edible Flour (Control) Order, 1967, Milk and Milk Products Order, 1992 etc will be repealed after commencement of FSS Act, 2006.

The Act also aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi- level, multi- departmental control to a single line of command. To this effect, the Act establishes an independent statutory Authority - the Food Safety and Standards Authority of India with head office at Delhi. Food Safety and Standards Authority of India (FSSAI) and the State Food Safety Authorities shall enforce various provisions of the Act.

FSSAI has been mandated by the FSS Act, 2006 for performing the following functions:

- Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
- Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
- Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.

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- To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
- Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
- Creating an information network across the country so that the public, consumers, Panchayats etc receive rapid, reliable and objective information about food safety and issues of concern.
- Provide training programmes for persons who are involved or intend to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
- Promote general awareness about food safety and food standards.

Initiatives of FSSAI for fixing of standards of food articles:

- Draft standards for caffeinated beverages have been formulated and are under notification for seeking public comments.
- Draft notification for fixation of limit of trans fatty acid in partially hydrogenated vegetable oil, has been notified for seeking public comments.
- Draft notification for fixing standards for antibiotics in Honey, has been notified for seeking public comments.
- Draft standards for olive oil have been notified for seeking public comments.
- Regulations of alcoholic drink - alcoholic drink has been defined as food under Food Safety and Standards Act 2006 and the process of framing standards and regulation thereof has begun. After following the prescribed process of standards setting, the same would be brought to the food authority for discussion.
- Draft regulations of imported food safety have been framed.

A**chievements of FSSAI so Far:**

- Food Commissioners in place 22 States and Union Territories
- FSS (Licensing and Registration of Food businesses) Regulations, 2011 operationalised in all states
- Over 2.77 lakh licences and 8.6 lakh registrations issued by the state governments till March 2013
- Over 9,000 licences issued at the Central level, till March 11, 2013

Areas of Concern:

- No clarity yet on overlaps among the definitions leading to potential confusion with companies may finding it difficult to adapt the new practices leading to delay in marketing new products
- Understaffed administration; Insufficient food sample testing labs
- Need for ample attention to inspection, requiring knowledgeable inspectors, who are educated and trained
- Food-medicine interface need to be analysed and regulated properly

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- Lack of clarity about when a product is main line food and when supplement
- Inadequate fund allocation

Regulatory Challenges

- Lack of establish rules & regulations for nutraceutical products, current governance have no clarity of operating segment in Healthcare sector under Section 22 (Proprietary Food).
- Ingredient standardisation will help create good standards and safety control rather asking for Product Approval which is making chaos and delaying execution of rules and regulations affecting the whole food industry.
- Exorbitant application fees for approval, no rationalisation which is unpractical affair this percolates down and impact the operational economy especially for Micro and Small companies.
- Referral of product for Scientific Committee assessment (with additional equal fees paid extra) for simple nutraceutical ingredients which are already in market overseas, even in India since years and having ample documentation on net. This system not forming specific rules under section 22 by itself will defeat the purpose for process. FBOs, inclusive of all streams, need final rules to comply will lead to challenges for both the government and industry.
- Site approval 'dependant' on Product Approval.
- Exorbitant repeated cost incurred by the FBOs travelling to Central Office for application filings. Lack of State/Zonal interface for PA applications.
- Variable advisories without established rules causing phenomenal confusions and uncertainties - resulting filing or re-filing of the dossier already with duplication of fees.
- New Business Opportunities/New Entrants/Innovation has become standstill impacting the complete sector under such ambiguous law with no clarity. Segregation of Proprietary Food rules is a must or else would be death of 9. Nutraceuticals sector in India as such we are invisible on the global graph.
- Product rejection done without scientific reasoning when Section 22 has not been framed.
- Lack of healthy dialogue with industry bodies to form co-operation by government and industry by understanding practical experiences, difficulties, limitations impacting ultimate to consumers with such uncertainties causing confusion and also considering the situation when future disease risk is very high if not supported with good and right supplements at the right time.
- RDA for nutrients imposed rather than upper tolerable limits which is the global norms to have better control of safety parameters and offer appropriate benefits of supplements in specific conditions/needs of individuals for good health. Early conclusions without evaluation and healthy dialogue will be the loss of good health for Indian Population.

Issues Related to Clinical Trials

Clinical research is an indispensable part of the drug discovery process to ensure the safety and efficacy of any new drug. In today's global scientific era, clinical trials are the mainstay for bringing newer and better drugs to market. A clinical trial, simply put is an experiment conducted to study if a new medication is safe and effective in the treatment of a particular medical condition. Because not much is known about the new medication at the time of a clinical trial, doctors are required to follow a rigorous schedule to oversee patient

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safety. Patients may be required to follow-up with the doctor more often than in routine practice and the doctor's team is expected to spend much more time with the patient than in routine practice. The objective is to allow patients access to better medicines in the future to come.

All clinical trials of new drugs need to be approved by the Drugs Controller General of India (DCGI) and the institute ethics committee (lEC) of the centre where the trial is to be carried out The trial would need to be registered in the Clinical Trials Registry - India (CTRI) hosted at the National Institute of Medical Statistics (NIMS) of the Indian Council of Medical Research (ICMR). The trial can be carried out only at a centre that has been accredited for carrying out clinical trials, and by a principal investigator who has been accredited for the same.

Clinical trials and India

India offers unique opportunities for conducting clinical trials due to a significant cost reduction and increased speed and productivity of all R&D phases required to bring a safe and effective drug to market.

India offers cost advantage. Depending on the number of patients and investigators, and the amount of analytical work completed in India, most sponsors will enjoy a 30-50% cost advantage over a similar trial in the US or Europe. Although the cost of labor is less, it is mandatory to make investments in training and support systems to ensure data quality. Support services such as printing, translation, and local courier fees are also less expensive. A study by Rabo India Finance found that phase I trials in India cost less than half of similar trials in the United States; Phase II and III trials cost less than 60% of their American equivalents.

At present, India can offer a considerably good and suitable infrastructure for conducting clinical trials. Tata Memorial Hospital in Mumbai, India, is an example of a specialty oncology center that is very well suited to participate in global clinical development. Each year 25,000 cancer patients visit this hospital, not only from India but also from neighboring countries. Each day, 1000 patients attend out-patient clinics and there are inpatient beds. Over 10,000 major operations are performed at Tata Memorial Hospital, and about 5000 radiotherapy and chemotherapy treatments are delivered each year. The centers equipped with state-of-the-art facilities, including spiral CT scanner, gamma cameras, linear accelerator, and bone marrow transplant facilities. In order to coordinate the ever increasing interest from international and domestic sponsors a Clinical Research Secretariat, Scientific Review Committee, and Ethics Committee have been established.

Regulation of clinical trials in India

Clinical trials, in addition to national laws, are governed by well established guidelines and directives at international level like EU regulations and directives. These guidelines and directives primarily aim at protecting the subject from taking undue risk in participating in a clinical trial; enforce both voluntary consent to research and the continual assessment of risk and benefit. In India, Central Drugs Standard Control Organization (CDSCO) (headed by Director Control General of India) is the primary authority and "Drugs and Cosmetics Act, 1940" (along with the rules framed there under) is the principal legislation for the regulation of clinical trials. Schedule Y of the Drugs and Cosmetics Rules, 1945 ("Rules") provides for the detailed conditions, and compliances relating to clinical trials in India.

Recently on 30th January 2013, Government of India came out with certain amendments to Schedule Y of the Rules with a view to tighten the norms relating to the conduct of clinical trials especially in terms of taking informed consents from the trial subjects and providing them or their legal representatives (as the case may be) compensation in case of any trial related injury or death. The amendment has imposed complete and

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ultimate liability on the sponsor of the clinical trial to reimburse any cost incurred by the trial subjects for the medical treatment of "any injury" suffered by the trial subjects as well as financial compensation for such injury or death. Further in case the sponsor fails to provide the proper medical treatment and/ or the financial compensation as per the orders of the licensing authority to the trial subjects (or their representatives as the case may be), then the authority may cancel or suspend the license of the sponsor to carry out the clinical trials and may even debar it from carrying any clinical trial in future in India. The amendment also mandates GCP compliance and adverse event reporting. The amendment has certainly acted as a deterrent on the multi-national corporations and is a negative catalytic agent to the prospects of clinical trials in India.

Issues and recommendations

One of the problems in our country is that people are not educated to the level where they can understand the concept of clinical trials. It is thus important that clinical trials are conducted in the presence of social worker(s). Every person who agrees to take part in the clinical trial should be informed and made to understand what it is all about, its benefits, the likely side effects, and the methods by which we can address the problems which one might face during the course of the trial.

Another critical facet of clinical trials is that people are not 'guinea pigs'. According to an affidavit filed by the health ministry in the Supreme Court in response to a petition by health NGOs, there were 80 deaths due to clinical trials between January 2005 and June 2012. Between July 2012-August 2013 nine more such reported deaths occurred, making this total 89, according to the petitioner Swasthya Adhikar Manch (SAM), a health rights forum. Compensation was paid in 82 cases. The ministry also admitted that 2,644 people died during clinical trials of 475 new drugs from 2005 to 2012.

Government documents also say that around 11,972 "serious adverse events" (excluding death) were reported from Jan. 1, 2005 to Jun. 30, 2012, of which 506 were said to have been caused by clinical trials.

These figures have raised new opposition to the prevailing practices for conducting clinical trials.

Compensation is another contentious issue that is being dealt with in the new directive. Between 2010-2012 the Drugs Controller General had approved 1,065 clinical trials. Activists say that taking advantage of poverty, illiteracy and lack of awareness, pharmaceutical companies or middlemen, even doctors, often connive to deny compensation to participants when due.

In all other cases of death or injury/disability, compensation should be paid to the participant or his legal heirs. The base amount and other calculations are still being worked out.

If a trial takes place anywhere in the developed world, the patient is adequately compensated for putting himself through a certain amount of risk. This aspect becomes even more critical when the vital parameters like liver function, kidney function, heart, and certain enzyme systems, of the individual patients are affected. These health concerns need to be carefully monitored and observed during the course of the drug trial.

In 2006, an investigation by health advocacy organisation WEMOS and the research organisation Centre for Research on Multinational Corporations (SOMO), both based in Amsterdam, prepared an overview of 22 unethical clinical trials around the world; eight of them were in India.

According to the health ministry, more than half the clinical trials are conducted by foreign pharmaceutical companies and the rest by clinical research organisations and domestic companies.

Demands have been raised for greater benefits to those undergoing trials.

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According to documents submitted by the Drugs Controller General of India in the Supreme Court, between January 2005 and June 2012 India approved 475 clinical trials for "new chemical entities" not used as drugs elsewhere in the world.

Meanwhile, the Supreme Court has extended its ban on clinical trials of 162 new drugs till Dec. 16, 2013, directing the government to ensure a "foolproof" mechanism for regulating the experiments by pharmaceutical companies.

There is a strong requirement for liberalizing the regulatory environment in favor of the sponsors conducting such trials and at the same time balancing the interest of the subjects involved in such trials. Further the approval mechanism needs to be more transparent and time efficient. Concerns raised by the human rights activist and NGOs are genuine, but rejecting or delaying the approval to the applications for conducting clinical trials is in no way a solution to the problem. Law should be for the "regulation" of the clinical trials and not for "restricting" the clinical trials. Instead of dismissing clinical trials or delaying the approval process, what is required is to identify and fix the loopholes in the regulatory framework and implement existing laws effectively to ensure that clinical trials are conducted with utmost transparency and diligence.

Following are some of the changes suggested for the growth of clinical trials in India:

1. **Informed consent:** Improvement in the system of obtaining informed consent from the subjects. Audio/ visual techniques of recording should be used while explaining the subjects about the process, the likely side effects and taking their consent. Further, subjects should be clearly informed about the past records of such clinical trials and number of adverse effects/deaths reported due to such clinical trials. Merely poverty and free treatment should not be the basis of engaging subjects in the clinical trials. Investigators and sponsor should be morally responsible in this regard.

2. **Restricting the liability of sponsors:** Restricting the liability of the sponsors to the injury or death of the subject which are resulting directly or sufficiently attributable to the participation of the subjects in the clinical trials. The timelines for payment of compensation should be liberalized depending upon the case to case basis. A fixed timeline in all type of adverse events and claims may not serve the purpose. Further the amount of financial compensation (over and above the cost of medical treatment) should be quantified or objective criteria to determine the same should be ascertained. For example, a terminally ill patient who chooses to be the subject of a clinical trial need not be given the same compensation as a healthy individual who has opted to become the subject for clinical trial. It should not be left at the sole discretion of the licensing authority or ethics committee.

3. **Institutionalization and registrations:** Independent research and trials should be restricted and only institutionalized clinical trials to be carried out. It is commonly seen that investigators and doctors at individual level carry out unregulated clinical research in private clinics and hospitals. This is required to be checked by the authorities. Registration of clinical trials with Clinical Trials Registry India and registration of clinical research organizations should be mandatory. This is already in place, however the effective implementation of the same should be ensured.

4. **Approval mechanism:** Fast and time efficient approval mechanism is required. Objective criteria for accepting or rejecting the applications, transparency in the entire process and the decisions for rejection or pending applications should be supported with the appropriate reasons. It is to be noted that the approval time for initiating drug trials in India typically runs from six to eight months, compared to 28 days in Europe and Canada.

5. **Transparency:** Transparency from the side of investigators and institutions is also very important. It is one of the core guiding principles in the ICMR Ethics Guidelines. Institutions and investigators should be open to public about regarding kind of investigation, standard of care taken, subjects involved, etc.

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6. **Inspection and auditing:** Officials of the CDSCO or licensing authority carrying out the inspection of the site should be of the same field with adequate knowledge and expertise on the subject. Also the use of CCTV camera at the trial site to administer the whole procedure of trial should be implemented. Further, involvement of the experts from the industry and legal field in the ethics committee and more emphasis on institutionalization of the ethics committee is also necessary. These would help the ethics committee and regulatory authority to investigate the matter more efficiently.

7. **Applicability of stringent laws:** Multi-national corporations which are voluntarily following the internationally recognized guidelines and directives or are governed by laws of other home countries which are materially equivalent strict in terms of following the good clinical standards and protecting the interest of the subjects, should not be made to comply with more procedural compliances and practices and should be provided a conducive regulatory atmosphere for coming to India and carrying out clinical trials.

8. **Drugs with serious side effects:** It is seen that most of the deaths occurred in the past few years is due to some specific drugs which were time and again put to investigation and every time resulted in the severe adverse effects. Special care should be taken in approving the clinical trials of such drugs and only in exceptional cases and depending upon the utility of such drug the permission should be given.

9. **Role of media:** Negative publicity of clinical trials and multi- national corporations involved in such trials should be avoided and discouraged. Media should be responsible in spreading any critical report relating to the clinical trials and same should be approved by the licensing authority in advance. In past Such negative publicity discourages the sponsor and creates uncertainties in the mind of the subjects. Rather media should emphasize on spreading awareness about such clinical trials targeting the vulnerable sections who mostly get involved in trials as subjects.

10. **Pending actions from the side of Government:** The proposal of Ministry of Health and Family Welfare with respect to forming a committee comprising of science and regulatory experts that would formulate policy on drug approvals, clinical trials and drug bans should be implemented promptly. Also the draft bill on Biomedical Research on Human Participants (Promotion and Regulation) prepared by the Indian Council of Medical Research should be tabled in the parliament on priority basis. It would be beneficial if the comments and suggestions of the experts from the industry are taken.

11. **Clarification:** Removing the loopholes in the language of the amended schedule Y (for instance as mentioned above the time period with respect to the reporting of serious adverse events) and bringing clarity to the same.

Strengthening and designing an appropriate evaluation method will definitely check misconduct. Forming Bioethics Centers in different states or at least in all metropolitan cites can improve the vigilance system on the ongoing trials. Adequate formal training of all the investigators, supervisors and data management staff will help in integrating ethical concerns in a better way and there is also need of introducing courses in government institutions tailoring the shortfalls. Networking between national and international trial centers help in reduction of mishaps in a way by prompt exchange of reports and data. It is the high time that health ministry should adopt hard steps to strong the regulatory mechanism to promote India a clinical trial heaven.

Issues Related to Patents in Pharma

The Indian Pharmaceutical Industry, particularly, has been the front runner in a wide range of specialties involving complex drugs' manufacture, development, and technology. With the advantage of being a highly organized sector, the pharmaceutical companies in India are growing at the rate of $ 4.5 billion, registering further growth of 8 - 9 % annually. More than 20,000 registered units are fragmented across the country and

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reports say that 250 leading Indian pharmaceutical companies control 70% of the market share with stark price competition and government price regulations.

- **Competent workforce:**

India has a pool of personnel with high managerial and technical competence as also skilled workforce. It has an educated work force and English is commonly used. Professional services are easily available.

- **Cost-effective chemical synthesis:**

Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

- **Legal & Financial Framework:**

India has a solid legal framework and strong financial markets. There is already an established international industry and business community.

- **Information & Technology:**

It has a good network of world-class educational institutions and established strengths in Information Technology.

- **Globalization:**

The country is committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is continuously growing.

- **Consolidation:**

For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a generalized phenomenon in the world pharmaceutical industry, has started taking place in India.

- **Policy support**

Government unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Reduced approval time for new facilities to boost investments

The Indian pharmaceutical Industry is driven by knowledge, skills, low production costs, quality. This has resulted in a robust growth of around 14% since the beginning of the 11th Plan from about Rs 71000 crores to over Rs 1 lac crores comprising some Rs 62,055 crores of domestic market and exports of over Rs 42,154 crores.

Patents in Pharma sector in India

A patent is a property right granted by a sovereign state to the inventor of a novel, non-obvious and useful invention. Because the invention must be novel (meaning that it has not been previously disclosed anywhere in the world) and because it cannot be obvious to one ordinarily skilled in the art, the grant of the property right cannot interfere with the public's access to what already exists.

The owner of a patent has the right to exclude others from making, using, offering for sale, or selling his or her invention for a period of 20 years from the filing of the patent application.

An invention is any new or useful process, machine, article of manufacture, or composition of matter. An improvement on any of these items also can be an invention. Patent rights are territorial in nature and exist

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only in the national jurisdictions in which the patentee has applied for and received recognition of his property rights.

Whether a claimed invention meets the tests of novelty and non-obviousness is determined by comparing it to the body of previously disclosed information in the same field. This information is usually called "prior art." The most commonly used prior art consists of published patents that have already been issued or published by the world's patent offices.

The benefit of granting an inventor the exclusive property right of a patent for the limited period of 20 years is that he or she is given a powerful incentive to create. The inventor is assured that investors will be given the incentive to commit the financial resources necessary to support the inventor's research and to develop it to the point where it can be manufactured and made available to the market.

The history of patents in India move as follows: The patent policy of India in the 1950 was to ensure that there was local production of drugs. In 1950, foreign multinational made the entire drugs supply in India. Foreign multinationals controlled more than 90% of the Indian pharmaceutical industry and hence determined supply and availability of drugs. Drugs were manufactured outside India and imported for a higher cost. The cost of drugs in India was amongst the highest in the world. Unable to control the expenditure on drugs the government of India took two significant steps to remedy the situation. First, the government signed an agreement with UNICEF to set up a factory for manufacturing of penicillin and other antibiotics. This resulted in the establishment of Hindustan Antibiotic Limited in 1957 to manufacture drugs at a cheaper rate for the public. Next, the government appointed justice Rajagopala-Ayyangar Committee in 1957 to recommend revision to the patent law to suit industrial needs. The object of the committee was to ensure India developed a locally sustainable pharmaceutical market. Hence the report recommended a compulsory licensing system and process patenting of drugs. The act based on the Ayyanger report and the rules came into force in 1972.

The patent policy pursued by India enabled it to become a big international player in the generic drug market. The patent policy of 1970 dramatically changed India's condition. In 30 years, the Indian pharmaceutical industry is valued at USD 70 billion compared to a mere USD 2.1 million before 1970. Currently 24000 pharmaceutical companies are licensed in India. Of the 465 bulk drugs used in India, approximately 425 are manufactured within the country. Indian industry has emerged as a world leader in the production of several bulk drugs. Indian industry has emerged as a leader for the production of bulk drugs like sulphamethoxazole and ethambutol. Indian production accounts for nearly 50% of the world production.

But due to launch of TRIPS, policy requires developing countries to only award product patents. Novel processes will not be patentable in developing countries since these countries do not use process by product claims. Consequentially, inventions patentable in developed nations by use of process by product claim will fall outside TRIPS compliant patent legislation of developing nations. Some generic drugs patentable in developed nation using process by product claim will be unprotected in developing nations.

TRIPS, the intellectual property component of the Uruguay round of the 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 LDCs. They also asserted that IPRs would benefit the developing countries like India by encouraging foreign investment, by enabling transfer of technology and greater domestic research and development (R&D). On the other side, LDC governments were worried about the higher prices that stronger IPRs would entail and about the harm that their introduction might cause to infant high tech industries.

Patent issue and Novartis Case

The Supreme Court in a recent landmark decision has rejected a patent application made by the drug manufacturer, Novartis AG **("Novatis")** in relation to its cancer cure drug Gilvec. This decision is a significant development in India's nascent patent regime.

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Brief introduction of case:

On 17 July 1998, Novartis filed an application before the Patent Office, Chennai for grant of patent on the beta crystalline form of Imatinib Mesylate **("Drug")**, which is used for the treatment of leukemia. On 25 January 2006, the Assistant Controller of Patents and Designs passed an order rejecting the patent claim filed by Novartis on the grounds that the invention claimed by Novartis was obvious, anticipated and that the grant of patent on the Drug is not permitted under Section 3(d) of the Patents Act, 1970 **("Patents Act")**. Against this order, Novartis filed an appeal in the Madras High Court, which was later transferred to the Intellectual Property Appellate Board **("IPAB")**. The appeal was rejected by the IPAB on 26 June 2009. Aggrieved by the rejection of grant of patent on the Drug, Novartis approached the Supreme Court. The Supreme Court in its judgment dated 1 April 2013 **("Judgment")** has upheld the rejection of Novartis' patent claim on the Drug.

Supreme Court Observations

The main question before the Supreme Court was that

1. Whether the invention qualifies the section 3(d) of the patent act?
2. Interpretation of section 3(d) of patent act?
3. Whether the invention qualifies for the test of novelty and inventive for the alleged product?

The main contention of Novartis was that IPAB admitted that the substance is an invention in its impugned order and then applied section 3d of the act, It was contended that if it is admitted that the product is an invention then section 3d would not be applicable as section 3d is applicable to incremental inventions or discovery and not on new invention.

It was also contended that 'efficacy'test is only applied on known substance but not in the case of beta-crystalline form of imatinib mesylate which is a new substance.

The approach of Supreme Court was simple in this case-:

1. Court observed that the product was a new form of substance not an entire new substance. It has always existed in the original amorphous form. The product thus qualifies for the test laid by section 3d of the patent act.
2. This section says that just discovering a new form of a substance is not enough to grant a patent, if it does not enhance its "known efficacy".
3. On interpretation of section 3d of the act, Novartis tried to argue that the physico-chemical properties of the polymorph form of the imatinib molecule, i.e. better flow properties, better thermodynamic stability and lower hygroscopicity, resulted in improved efficacy. The Supreme Court firmly rejected this contention holding that in the case of medicines, efficacy means "therapeutic efficacy" and these properties while they may be beneficial to some patients do not meet this standard. The Supreme Court also held that patent applicants must prove the increase in therapeutic efficacy based on research data in vivo in animals.
4. Simply if the invention does not qualify the test of Therapeutic efficacy the invention can't be granted patent, Thereby the true intention of the section 3d of patent act is fulfilled by stopping the concept of ever greening in critical sectors, moreover the supreme court held the strict view that patent in the field of medicine specially in the cases of life saving drug must be granted with full caution so that larger interest of the masses are not affected to an extent that they lose right to live.

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The SC judgement is a big relief for those people who can't afford the lifesaving drugs manufactured by profit guzzling big pharma giants, there is a simple sense of humanity which needs to be preserved by the human race only. The Company in the name of patent prohibits those generic firms who are selling the generic version at an affordable rate, These Pharma big giants are corporates and claimed to have already made billion dollars and are becoming selfish thereby prohibiting people to buy the cheaper version and leaving only option to die because of the fact they are poor as if these Big pharma giants have a patent rights over their lives.

The Supreme Court was clear that India is a developing country and cheap medicines are an essence for healthcare of 1 billion people. The Supreme Court has taken a right step and thereby prohibited the liberal approach in granting patents and thus filtering the genuine inventions with frivolous inventions which allows these companies to make huge amount of inventions.

Issues:

As with any new law, post-TRIPS patent regime has brought new challenges in India as it involved some significant changes in the patent law.

Some issues are discussed below:

- **Patent administration**

The key issues in patent administration include pendency, access to information, challenges with respect to enforcement. One of the main reasons cited for low pendency is due to the high workload of examiners to examine applications. India clearly has more work load than many other countries.

Currently filing of patent applications is allowed electronically and does not allow the electronic facility to file for responses to the objections raised by the IP office. As a result those not residing in the location where branches of patent offices are set up, causes them a great issue as they have to either travel down to that place to communicate with examiners or hire some attorneys located in those areas.

- **Compulsory Licence**

Rights of the TRIPS member countries to make use of compulsory licensing in the interest of public health have been explicitly recognized in the Doha Declaration on Public Health. Although TRIPS does allow compulsory licences, it has been noticed, from interaction with patent experts and media reports that business advantages are not necessarily given the go by and that usage of compulsory licence is subject to a due adjudication process. Whilst grant of compulsory licence is itself the exception than the rule, yet corporate strategies do try to safeguard companies absolutely, through other restrictive methods. Most of the times, economic and political factors also make it difficult to invoke the basic legal instruments to access these services. The courts in India, even otherwise, have relied on validation of compulsory licencing on the grounds of public welfare.

- **Patentability Criteria**

There appear to be tendencies to create piles of patents, which are successively filed every 20 years so as to create a superstructure of knowledge, patented by the originator. Argumentatively analysing these business strategies, it can be realised that such stockpiling of patents brings down the real space within which generic drugs industry could innovate. Such piling up leads to a lockdown of knowledge space and is likely to have telling effects on research energies.

Section 3(d) of the Indian Patents Act does not allow ever-greening, as it defines inventions as to be those that improve the known efficiency of an existing formulation or those that involve discovery/invention of an entirely new property. However, this provision is under challenge in the Supreme Court of India.

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- **Patent validity**

It is also interesting to note that grant of Patent under Indian law does not tantamount to validity of the said patent. As per the provision of section 13(4) of the Patents act, the grant of patents by the patent authority does not confirm the validity of a patent and as such no liabilities are incurred by the central government or any agencies thereof. One of the reasons why the Drug Controller under the Drugs and Cosmetics Act is not charged with duties to look into the validity of patent before granting marketing approvals is based on this section, since if the Drug Controller is charged contrarily, it leads to presumption that a patenting implies validity, something which is specifically denied vide sec 13(4) of the Patent Act. It is also not clear why Drug Controller should also look at validity of patents when other regulators of this nature do not look into such issues.

- **Awareness and capacity of stakeholders**

Micro Small and Medium Enterprises (MSME) play a vital role in the Indian economy and are considered an engine of economic growth and equitable development which touch upon the lives of the most vulnerable, most marginalized and the most skilled. They address the national priorities of employment generation (with the sector being the second largest employer after agriculture and creating this employment at low capital cost), poverty reduction and regional imbalances. As per the available statistics from the 4th Census of MSME Sector there were an estimated 59.7 million persons spread over 26.1 million enterprises. The MSMEs in India provide employment to an estimated 31.2 million people in the urban and rural areas of the country. The sector is also a significant contributor to the output/income of the manufacturing sector and towards the gross national product (GNP). It is estimated that in terms of value, MSME sector accounts for about 45 per cent of the manufacturing output, 6% of GDP and around 40 per cent of the total exports of the country.

Despite playing such an important role for the Indian economy, the SME sector has not exploited IP rights to protect their innovation. It is commonly perceived by the SMEs that high-level technology such as "revolutionary inventions" can only be patented. Indian SMEs are not coming forward to adopt IPR as a business strategy.

Stakeholders feel that one of the most important reasons behind this is widespread lack of awareness about IPR. SMEs sometimes fail to understand that registering IP can consolidate market position; provide new revenue streams through licensing, franchising or sale; increase investment funds to develop and market new products, and substantially increase negotiating power through cross licenses or joint venture agreements.

Indian companies need to attain the right product-mix for sustained future growth. Core competencies will play an important role in determining the future of many Indian pharmaceutical companies in the post product-patent regime after 2005.

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