OVERVIEW OF PHARMACEUTICAL INDUSTRY WITH SPECIFIC REFERENCE TO PHARMACEUTICAL LAWS OF INDIA

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1. INTRODUCTION

"The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent."

The main aim of the Pharmaceutical Industry is to develop, research and distribute drugs in order to provide health care for the people in the society. Pharmaceutical companies are allowed to deal in generic and/or brand medications and medical devices. Just like any other industry, they are also subject to various rules and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs.

Since the inauguration of the Pharmaceutical Industry in the 19th century, it has covered a long way and now it has become one of the most influential and successful industry in the world with both controversy and praise on its part.

The word pharmaceutical comes from the Greek word 'Pharmakeia' meaning practice and making of medication and vitamins. The modern transliteration of Pharmakeia is 'Pharmacia' which means pharmacy, the making and dispensing of poisons, pharmaceuticals or medicines as well as cosmetics, lotions, perfumes etc.

1.1. Meaning of Pharmaceuticals, Pharmacy, Drugs, Medicines etc.

Pharmaceuticals means, pertaining to the knowledge or art of pharmacy; or to the art of preparing medicines according to the rules or formulas of pharmacy; as, pharmaceutical preparations.

Pharmacy means the art or practice of preparing and preserving drugs, and of compounding and dispensing medicines according to prescriptions of physicians.

Pharmaceutical Drugs are defined as chemical substances used for treating, curing and preventing different types of diseases. Commonly referred to as medicines or medication, pharmaceutical drugs are used in the medical diagnosis, treatment,

prevention or curing disease. Medicines help in fighting or preventing diseases if they are taken in the right quantity at the right time and as prescribed by the doctor.

These medicines either are prescriptive or non prescriptive.

Administration of a drug means how the drug is delivered to a patient. Pharmaceutical drugs are available in the forms of pills, tablets, capsules and syrups. They can be taken orally or intravenously (into the blood through a vein). They are administered at regular intervals or all at once depending on doctors' advice.

1.2. Prescription and Non prescription drugs

Prescription drugs are drugs that are not locally available without a physician's prescription. A prescription drug is a licensed medicine which is obtained only by prescription. The prescription drugs are regulated by legislation and different from over-the-counter (OTC) drugs which can be obtained without a prescription. The term "Rx" is often used as a short form for prescription drug. Any kind of prescription drug will usually have a monograph or Patient Information Leaflet (PIL) that gives detailed information about the drug.

List of Prescription drugs –

1) Anti-convulsant Drugs
2) Anti-Obesity Drugs
3) Anti-Angina Drugs
4) Anti-Fungal Drugs
5) Anti-Itch Drugs
6) Anti-Viral Drugs
7) Anti-Diabetic Drugs
8) Anti-Asthmatic Drugs

9) Anti-Hypertensive Drugs

10) Antibiotics

11) Anti-Migraine Drugs

12) Anti-Rheumatic Drugs

13) Anti-Protozoal Drugs

14) Tricyclic Anti-depressants

15) Anti-Arrhythmic Drugs

16) Anti-nausea Drugs

17) Anti- Parkinson Drugs

18) Anti-Psychotic Drugs

19) Muscle Relaxants

20) Digitalis Drugs

21) Anti-Gastroesophageal Reflux Drugs

22) Anti-Retroviral Drugs

23) Anti-Tuberculosis Drugs

24) Anti-Ulcer Drugs

25) Anti-Hemorrhoid Drugs

26) Anti-Spasmodic Drugs

27) Anti-malarial Drugs

28) Non-steroidal Anti-inflammatory Drugs (Some can be bought over the counter; others are available only with a prescription from a physician or dentist)

29) Immuno-Suppressant Drugs

30) Anti-Insomnia Drugs

31) Anti-helminthic Drugs

32) Central Nervous System Stimulants

33) Decongestants: (Some decongestant products require a physician's prescription but there are also many non-prescription (over-the-counter) products.)

34) Anti-Coagulant Drugs

35) Bone Disorder Drugs

36) Infertility Drugs

37) Topical Antibiotics: (Some topical antibiotics are available with a prescription only.)

38) Diuretics

39) Vasodilators

40) Blood-viscosity Reducing Drugs

41) Beta Blockers

42) Corticosteroids

43) Benzodiazepines

44) Cephalosporins

45) Expectorants: (Some are available only with a physician's prescription)

46) Sulfonamides

47) Calcium Channel Blockers

48) Gout Drugs

49) Anti-histamines: (Some Anti-histamine products are available only with a physician's prescription.)

50) Penicillins

51) Barbiturates

52) Laxatives

53) ACE inhibitors

54) Anti-anxiety Drugs

55) Urinary Anti-infectives

56) MAO Inhibitors

57) Opioid Analgesics

58) Bronchodilators

59) Ophthalmic Antibiotics

60) Smoking Cessation Drugs: (Some products are available only with a prescription.)

61) Protease Inhibitor

62) Anti-depressant Drugs

63) Alpha1-adrenergic Blockers

64) Tetracyclines

Non prescription drugs are drugs that are sold over the counter, which means they are sold without a prescription from a doctor. These drugs are sold directly to the consumers as compared to prescription drugs, which require a prescription. They are

also referred as the over-the-counter (OTC) drugs. There are more than 80 therapeutic categories of non-prescription drugs, ranging from weight control drugs to anti-acne to analgesics drugs and many more. These drugs are easily available in local chemists as well as in general stores, supermarkets etc. Non- prescription drugs usually have the following characteristics –

- The benefits of these drugs outweigh their risks.
- There are low chances for misuse and abuse.
- Consumer can use them for self-diagnosed health conditions.
- These drugs can be adequately labelled.
- There is no requirement of health professionals for the safe and effective use of the product.

List of Non-prescription drugs

1) Anti-Haemorrhoid Drugs
2) Topical Antibiotics: (Some topical antibiotics are available without a prescription)
3) Cough-Suppressants
4) Anti-acne Drugs
5) Non-steroidal Anti-inflammatory Drugs: (Some can be bought over the counter; others are available only with a prescription from a physician or dentist.)
6) Antiseptics
7) Analgesics
8) Decongestants: (Some decongestant products require a physician's prescription but there are also many non-prescription (over-the-counter) products.)

9) Aspirin

10) Vasodilators: (Some Vasodilators such as Minoxidil are sold without prescription.)

11) Antacids

12) Expectorants: (Many expectorants are available without a physician's prescription.)

13) Anti-Histamines: (Some can be bought without prescription.)

14) Anti-gas Agents

15) Smoking Cessation Drugs: (Many drugs can be bought over the counter, without prescription.)

1.3. Meaning of Biotechnology

The term "biotechnology" refers to the use of living organisms or their products to modify human health and the human environment. The United Nations Convention on Biological Diversity defines biotechnology as "Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

In other terms: "application of scientific and technical advances in life science to develop commercial products" is biotechnology.

Modern biotechnology can be used to manufacture existing medicines relatively easily and cheaply. The first genetically engineered products were medicines designed to treat human diseases. Modern biotechnology has evolved, making it possible to produce more easily and relatively cheaply human growth hormone, clotting factors for haemophiliacs, fertility drugs, erythropoietin and other drugs

1.4. Relationship between pharmaceuticals and biotechnology

Modern pharmaceutical manufacturing techniques frequently rely upon biotechnology.

Amongst the earliest uses of biotechnology in pharmaceutical manufacturing is the use of recombinant DNA technology to modify *Escherichia coli* bacteria to produce human insulin. Prior to the development of this technique, insulin was extracted from the pancreas glands of cattle, pigs, and other farm animals. While generally efficacious in the treatment of diabetes, animal-derived insulin is not indistinguishable from human insulin, and may therefore produce allergic reactions.

Prior to the use of recombinant DNA technology to modify bacteria to produce human growth hormone, the hormone was manufactured by extraction from the pituitary glands of cadavers, as animal growth hormones have no therapeutic value in humans. Production of a single year's supply of human growth hormone required up to fifty pituitary glands, creating significant shortages of the hormone.

Prior to the development and FDA approval of a means to produce human blood clotting factors using recombinant DNA technologies, human blood clotting factors were produced from donated blood that was inadequately screened for HIV. Thus, HIV infection posed a significant danger to patients with haemophilia who received human blood clotting factors.

Recombinant DNA techniques have also been employed to create transgenic farm animals that can produce pharmaceutical products for use in humans.

2. HISTORY OF PHARMACEUTICAL INDUSTRY IN THE WORLD

The earliest drugstores date to the Middle Ages since 18th AD. The first known drugstore was opened by Arabian pharmacists in Baghdad in 754, and many more soon began operating throughout the medieval Islamic world and eventually medieval Europe. By the 19th century, many of the drugstores in Europe and North America had eventually developed into larger pharmaceutical companies.

Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin (insulin is provided within the body in a constant proportion to remove excess glucose from the blood, which otherwise would be toxic) and penicillin (used in the treatment of bacterial infections), became mass-manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit.

Legislation was enacted to test and approve drugs and to require appropriate labeling. Prescription and non-prescription drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques.

Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, "The Pill", Cortisone, blood-pressure drugs and other heart medications. MAOinhibitors, chlorpromazine (Thorazine), Haldol (Haloperidol) and the tranquilizers ushered in the age of psychiatric medication. Valium (diazepam), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to controversy over dependency and habituation.

Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and

Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new anti-emetic in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs.

Cancer drugs were a feature of the 1970s. From 1978, India took over as the primary center of pharmaceutical production without patent protection.

The industry remained relatively small scale until the 1970s when it began to expand at a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products came into force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country.

The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation. Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process.

Managed care and Health maintenance organizations (HMOs) spread during the 1980s as part of an effort to contain rising medical costs, and the development of preventative and maintenance medications became more important. A new business atmosphere became institutionalized in the 1990s, characterized by mergers and takeovers, and by a dramatic increase in the use of contract research organizations for clinical development and even for basic R&D. The pharmaceutical industry

confronted a new business climate and new regulations, born in part from dealing with world market forces and protests by activists in developing countries. Animal Rights activism was also a challenge.

Marketing changed dramatically in the 1990s. The Internet made possible the direct purchase of medicines by drug consumers and of raw materials by drug producers, transforming the nature of business. In the US, Direct-to-consumer advertising proliferated on radio and TV because of new FDA regulations in 1997 that liberalized requirements for the presentation of risks. The new antidepressants, the SSRIs, notably Fluoxetine (Prozac), rapidly became bestsellers and marketed for additional disorders.

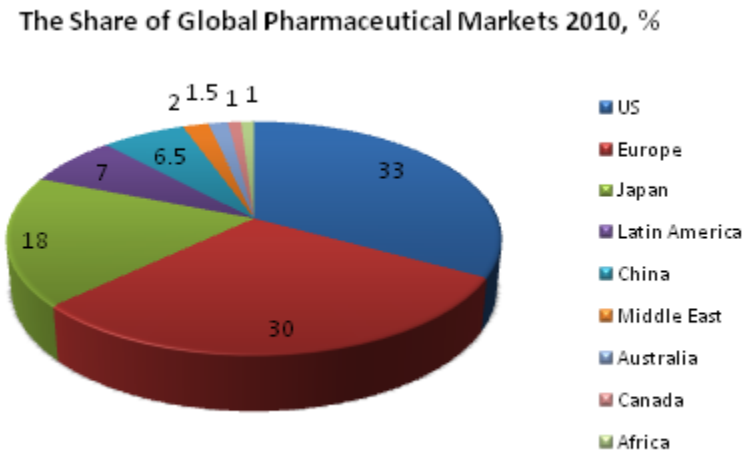
Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.

2.1. Present scenario of Pharmaceutical Industry in the world

The global pharmaceutical industry, after experiencing a shrink during the past 2 years, is now in its recovery period, which will be followed by its growth. Decline in global pharmaceutical market was largely due to the economic recession. Meanwhile, pharmaceutical markets in some developing regions, like Asia and Latin America have been continuously witnessing huge growth rate for the last few years on account of increasing prevalence of diseases, rising healthcare spending, and increasing affordability.

IMS Health (a global company that provides information, services and technology for the healthcare industry) reports that the total value of the global pharmaceutical market is expected to grow by 5–7% in 2011 to US$880 billion, compared with a 4-5% pace in 2010. While the value of the global pharmaceutical market, as expected,

increased by 7% in 2011 to US$880 billion. United States is still the largest pharmaceutical market in the world with a market size of around $300 billion and it is expected to reach $370 to $390 billion by 2015.



Today's major pharmaceutical markets, consisting of 17 countries, are slated to grow in the range of 15-17% in 2012, representing sales of $170-$180 billion. China, which is now the third largest market in the world, is expected to grow 25-27% to more than $50 billion in 2012. As far as developed markets are concerned, Japan is slated to grow 5-7% in 2012. Major European markets like the UK, Germany, France, Italy and Spain are expected to deliver combined growth of 13%.

According to Global Pharmaceutical Market Forecast to 2012, global pharmaceutical industry is projected to grow at a CAGR of around 6.5% during 2011-2013. The growth will be driven by low cost factor, increasing prevalence of diseases worldwide, and rising per capita income of consumers.

3. PHARMACEUTICAL INDUSTRY IN INDIA

The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95 per cent of the country's pharmaceuticals needs. The Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously.

Indian pharmaceutical industry is one of the most vibrant sectors of Indian industry and has maintained a growth of 11-12%. It is 3rd largest in the world by volume. The total size of the Indian Pharmaceutical Industry is about Rupees 1,00,000 crore out of which exports account for Rupees 42,000 crore and the rest is the size of the domestic market. It is 8% of global Production and 2% world Pharma market. India has the highest number of USFDA approved plants outside USA. There are 169 USFDA approved manufacturing facilities in India. Indian pharma companies are filing highest Abbreviated New Drugs Approval (ANDA) applications in USA. Further, there are 153 manufacturing facilities in the country which have been certified by European Directorate of Quality Medicine (EDQM) for export of drugs to European Union.

Playing a key role in promoting and sustaining development in the vital field of medicines, Indian Pharma Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK. Several companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in and helped to put India on the pharmaceutical map of the world.

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units with severe price competition and government price control. It has expanded drastically in the last two decades.

There are about 250 large units that control 70 per cent of the market with market leaders holding nearly 7 per cent of the market share and about 8000 Small Scale Units together which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce the complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

Indian pharmaceutical industry is mounting up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented global presence, providing wide range of value added quality products and services, innovation, product life cycle management and enlarging their market reach. The old and mature categories like anti-infectives, vitamins, analgesics are de-growing while, new lifestyle categories like Cardiovascular, Central Nervous System (CNS), Anti Diabetic are expanding at double-digit growth rates.

The reasons for growth of the Indian Pharmaceutical Industry in a nutshell:

- Indian Pharmaceutical Industry has reached a point which not only fulfills the demand within the country but also a surplus is generated for export purpose.
- The low production cost has also helped the Indian cause.
- A very low R&D cost has also proved helpful.
- Indian Pharmaceutical Industry has scientific power which is innovative in nature and has helped a lot.
- National Laboratories have also helped the cause by inventing various medicines.

3.1. History of Pharmaceutical Industry

Indigenous medicines were in use even prior to the British rule in India. Western medicine- scientifically termed as allopathic came to be known only during the British Era. The pioneering efforts of some few indigenous people led to the steady establishment of the modern pharmaceutical industry, even though the then British Government did set up some medical schools for education in modern pharmaceutical research. The Bengal Chemical and Pharmaceutical Works (BCPW) established in 1892 is an example in this regard. Subsequent efforts by others have also been duly recorded. Drug production meeting around 13% of Indian requirement was produced by several other indigenous firms during and after the Second World War. By 1930's efforts were also made in the direction of producing synthetic bulk drugs.

Before the therapeutic revolution, there wasn't much difference between the activities of indigenous and foreign firms in India since they were essentially manufacturers and not inventors. Indigenous sector dominated the pharmaceutical industry in India until 1950. The therapeutic revolution led to the change in equations between Indian pharmaceutical industry and global multinationals. 1940's and 1950's saw new medicines being marketed by (Multinational Corporations) MNC's in India. But indigenous industry remained unaffected by the change in dynamics. The focus was exclusively on manufacturing and not on research. This in a way strengthened the skills in developing new manufacturing technologies. A collaborative effort between Council of Scientific and Industrial Research (CSIR) and private manufacturing industry led to development, application and advancement of substantial skills in the pharmaceutical industry in India. However, post 1950 MNC's gained the ground with new medicines being introduced in the Indian markets. A strong product patent system then prevailing under the British Patents and Designs Act, 1911 (prevailing in India even after independence) led to increasing influence of MNCs in the Indian pharmaceutical markets. The Government seemed not to be initially concerned to create national champions during that period. A faulty system of industrial licensing exuberated the problem, as it leaned in favour of easy entry for MNCs prior to 1970s

even at the peril of indigenous industry. This was also because MNCs carried certain special type of processing of formulations, which was not carried out by Indian companies during that period. India was one of the unique countries which provided for special and national treatment to MNCs. Thus by 1970s, the share of indigenous companies was reduced from 62% (1950) to 32% in 1970. The share of MNCs stood at 68% in 1970s, which increased from 32% held in 1952.

However, it must be noted that during this period, the government established the IDPL and HAL with both indigenous and foreign technology collaboration. This provided the necessary impetus to the private industry players and instilled some confidence during the later stages of pharmaceutical industry development. The contribution of the CSIR laboratories is also well recognised for the private sector having developed substantial reverse engineering skills post 1970.

During late 1960s and in 1970s, there was a conscious attempt to give preference to national industry. This was in consequence to foreign monopoly dominating in the Indian health care sector. The socialist policy advocated by the government of the day and comprehensive review of legislations and policies having a potential to impede domestic participation paved the way for growth of the domestic generic industry in India. After a thorough review of the Patents and Deigns Act, 1911, the Ayyangar report examining the legislation came to a conclusion that foreign patent holders dominated the industry through large number of filing and grants. It viewed that the then prevailing patents law failed to work in “national interest”. Thus came in to being the Patents Act, 1970 – which limited patents only to process in case of pharmaceuticals and agricultural chemicals. Further the term of patents was also reduced to 7 years. Apart from this, the Foreign Exchange Regulation Act, 1973 and the National Drug Policy, 1978 provided essential impetus to the growth of the Indian generic industry. Thus post 1970 reversed foreign domination of the pharmaceutical industry in India. Large scale bulk drug production was possible and this led to the change in industry landscape.

A decade later, in late 1980 and early 1990, the Indian generic industry steadily increased the exports and came to be recognised as an important player in global generic industry. Substantial price controls initiated in 1979 through the Drug Price Control Orders, based on National Drug Policy, 1978 were pioneering efforts in the direction of ensuring equitable access to health. This led to entry of large number of firms thus contributing to the fundamentals of the present top generic companies in India. The technical skills augmented by the generic industry in reverse engineering pharmaceutical products developed elsewhere are also remarkable. Reverse-engineering though leading to the same product as that of the originators, involves the investment of substantial time, skill and capital investment. After 1990s, export led growth and increase in domestic consumption led to a dominating share of Indian firms in the market. In 1998, the domestic companies held 68% of the market share which grew to 77% in 2003.

Even in the new economic context of liberalization, privatization and globalisation, the foreign companies faced substantial barrier in penetrating into the Indian markets. However, post 2005, the Industry has been witnessing new trends and the landscape is fast changing. The large and the medium industry are attempting to strategize themselves in the changing landscape. The generic industry is having a different bargain contributed by increasing technical collaborations and a recent spate of mergers and acquisitions.

3.2. Growth scenario

The Indian Pharmaceutical Industry has grown from a mere US$ 0.3 billion (Rs.237 crore) turnover in 1980 to about US$ 21.73 billion (Rs.104,209 crores) in 2009-10. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value (1.5%).

In fact the annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 1,04,944.35 Crores during the year 2010-11. The share of export of Drugs, Pharmaceuticals and Fine Chemicals is more than Rs. 47551.26 crore.

The domestic Pharma Industry has recently achieved some historic milestones through a leadership position and global presence as a world class cost effective generic drugs' manufacturer of AIDS medicines. Many Indian companies are part of an agreement where major AIDS drugs based on Lamivudine, Stavudine, Zidovudine, Nevirapine are supplied to Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa. Many US Schemes are sourcing Anti Retrovirals from Indian companies whose products are already US FDA approved.
According to a report by McKinsey Global Institute, healthcare sector in India grew from 4% of average household income in 1995 to 7% in 2005, and is expected to grow to 13% by 2025. According to the same report, if the Indian economy continues on its current high growth path, then the Indian pharmaceuticals market will undergo a major changes in the next decade. It is expected that the market will triple to US$ 20 billion by 2015 and can easily become one of the world's top-10 pharmaceuticals markets. The absolute growth of US$14 billion will be next to the growth potential of the US and China, and the country is in the same league as the growth in Japan, Canada and the UK. n terms of scale, the Indian pharmaceutical market is ranked 14th in the world. By 2015, it will rank among the top 10 in the world, overtaking Brazil, Mexico, South Korea and Turkey.

There was another report by RNCOS titled "Booming Pharma Sector in India" in which it was projected that the pharmaceutical formulations industry is expected to prosper in the same manner as the pharmaceutical industry. The domestic formulations market will grow at an annual rate of around 17% in 2010-11, owing to increasing middle class population and rapid urbanisation.

Indian Pharma growth has been fuelled by exports and its products are exported to a large number of countries with a sizeable share in the advance regulated markets of US and Western Europe.

Value of Import and Export of Pharmaceuticals during 2010-11

Import / export	**Value** **(Rs. – Crores)**	**Growth** **(%)**
Import of medicinal and pharmaceutical products	10,937	9.82
Exports of Drugs and Pharmaceuticals and Fine Chemicals	47,551	12.00

4. REGULATORY FRAMEWORK

Historical perspective

In the beginning of the 19th century Drug Industry was practically non-existent in India and pharmaceuticals were being important from abroad. The First World War changed the situation and not only were finished and cheap drugs imported in increasing volume, the demand for indigenous products also were voiced from all sides. With the clamour for swadeshi goods manufacturing concerns, both Indian and Foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Naturally some of these were of inferior quality and harmful for public health. The Government was, therefore, called upon to take notice of the situation and consider the matter of introducing legislation to control the manufacture, distribution and sale of drugs and medicines.

Two of the laws, The Poisons Act and the Dangerous Drugs Act were passed in 1919 and 1930 respectively. The Opium Act was quite old having being adopted as early as 1878. But to have a comprehensive legislation, which the rapid expansion of the pharmaceutical production and drug market required by the end of the second decade for its control, the Indian Government appointed, in 1931, a Drugs Enquiry Committee under the Chairmanship Lt. Col. R. N. Chopra which was asked to make sifting enquiries into the whole matter of drug production, distribution and sale by inviting opinions and meeting concerned people. The Committee was asked to make recommendations about the ways and means of controlling the production and sale of drugs and pharmaceuticals in the interest of public health. The Chopra Committee toured all over the country and after carefully examining the data placed before it, submitted a voluminous report to government suggesting creation of drug control machinery at the centre with branches in all provinces. For an efficient and speedy working of the controlling department the committee also recommended the establishment of a well-equipped Central Drugs Laboratory with competent staff and experts in various branches for data standardization work. Under the guidance of the Central Laboratory, it was suggested, small laboratories would work, in the provinces.

For the training of young men and women, the Committee recommended the permission of Central Pharmacy Council, and the Provincial Pharmacy Councils, with registrars who would maintain the lists containing names and addresses of the licensed pharmacists.

The outbreak of the Second World War in 1939 delayed the introduction of legislation on the lines suggested by the Chopra Committee which the Indian government contemplated and considered as urgent. However, the Drugs Act was passed in 1940 partly implementing the Chopra recommendations. With the achievement of independence in 1947 the rest of the required laws were put on the Statute Book. In 1985, the Narcotic Drugs and Psychotropic Substances Act was enacted repealing the Dangerous Drugs Act 1930 and the Opium Act of 1878.

List of laws governing the pharmaceutical sector

1) National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)
2) The Drugs and Cosmetics Act, 1940
3) The Drugs and Cosmetics Rules, 1945
4) The Pharmacy Act, 1948
5) The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
6) The Narcotic Drugs and Psychotropic Substances Act, 1985
7) The Narcotic Drugs and Psychotropic Substances Rules, 1985
8) The Prevention of illicit traffic in Narcotic Drugs and Psychotropic Substances Act, 1988
9) Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 1993
10) Drug Policy 1986

11) The Medicinal and Toilet Preparations (Excise Duties) Act, 1955

12) The Medicinal and Toilet Preparations (Excise Duties) Rules, 1956

13) The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)

14) Clinical Establishments (Registration and Regulation) Act, 2010

15) Clinical Thermometers (Quality Control) Order, 2001

16) Good Laboratory Practice (GLP) Guidelines

17) Guidelines for I.V Fluids distribution, storage and administration

18) Guidelines for Blood Banks

19) Good Clinical Practice Guidelines

20) Guidelines for import and manufacture of medical devices

21) Guidelines on Recall and Rapid Alert System for Drugs

22) Guidelines on Fixed Dose Combinations (FDC)

23) The Patents Act, 1970

24) The Industries (Development and Regulation) Act, 1951

25) Trade Marks Act, 1999

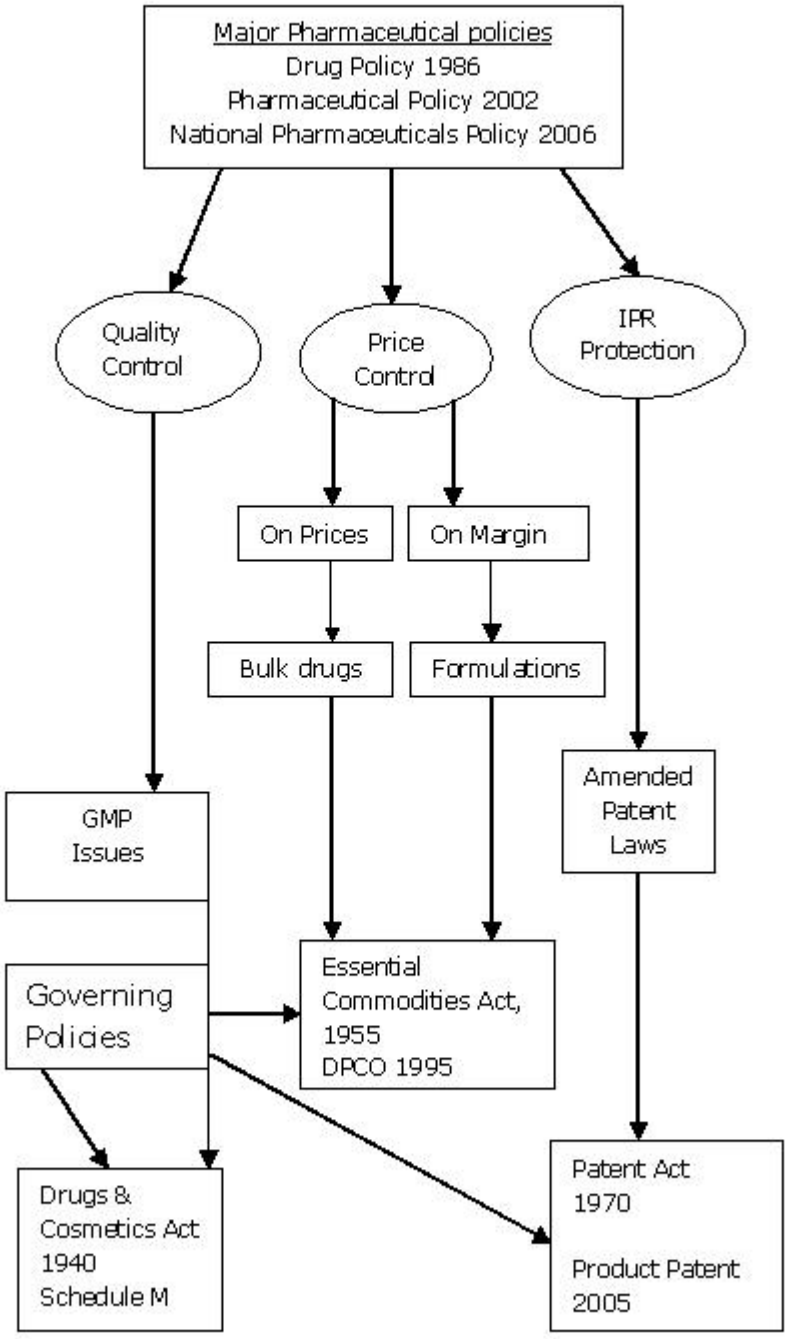
26) Labour related laws

27) Foreign Exchange laws

28) Taxation laws

29) Environmental laws

Regulatory control of Pharmaceutical sector



4.1. Overview of Drug related laws

1) The Drugs and Cosmetics Act, 1940 & The Drugs and Cosmetics Rules, 1945

The manufacture, import, distribution and sale of drugs and cosmetics in India is regulated by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945. This is mainly to maintain high standards of medical treatment otherwise substandard medicines may cause severe damage to the lives of people.

All Medicines including Ayurvedic, Siddha, and Unani, for internal or external use of human being or animals and all substances (other than food) intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparation applied on human body or to destroy insects are covered under the Act.

The Act consists of 38 sections under 5 chapters and 2 schedules.

The Rules consists of 168 rules under more than 19 Parts, 18 schedules and 11 appendixes.

Important terms under the Act

"Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of [8][disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of [9][Ayurvedic, Siddha and Unani Tibb systems of medicine], specified in the First Schedule. (Sec.3(a))

"**Cosmetic**" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic. (Sec.3(aaa))

"Drug" includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(*ii*) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board; (Sec.3(b))

"**Manufacture**" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly. (Sec.3(f))

"**Patent or proprietary medicine**" means, --

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulate described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by

parental route and also a formulation included in the authoritative books as specified in clause (a);

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5. (Sec.3(h))

Adulterated drugs

A drug shall be deemed to be adulterated, -

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength. (Sec.9-A)

Misbranded drugs

A drug shall be deemed to be misbranded, -

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
(b) if it is not labeled in the prescribed manner; or
(c) if its label or contained or anything accompanying the drug bears any statement, design or device which is false or misleading in any particular.

Spurious drugs

A drug shall be deemed to be spurious, -

(a) if it is imported under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or contained the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is only truly a product.

The Drugs Technical Advisory Board, the Central Drugs Laboratory & the Drugs Consultative Committee

The Act provides for constitution of Drugs Technical Advisory Board to to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act.
The Act also provides for the constitution of the Central Drugs Laboratory and the Drugs Consultative Committee.

There exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities.

State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.

Import of drugs and cosmetics

According to Sec.10 of the Act, no person should import –

- any drug or cosmetic which is not of standard quality;
- any misbranded drug or misbranded or spurious cosmetics;
- any adulterated or spurious drug;
- any drug or cosmetic for the import of which a licence is prescribed, then in accordance with, such licence;
- any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;
- any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;
- any cosmetic containing any ingredient, which may render it unsafe or harmful or use under the directions indicated or recommended;
- any drug or cosmetic the import of which is prohibited.

Small quantities of drugs, the imports of which is otherwise prohibited under Section 10 of the Act, may be imported for personal use subject to the following conditions -

- The drugs shall form part of a passenger's bona fide baggage and shall be the property of, and be intended for, the exclusive personal use of the passenger;

- The drugs shall be declared to the Customs authorities if they so direct;
- The quantity of any single drug so imported shall not exceed one hundred average doses.

Provided that the licensing authority may in an exceptional case in any individual case, sanction the import of a larger quantity.

Provided further that any drug, imported for personal use but not forming part of bona fide personal baggage, may be allowed to be imported subject to the following conditions, namely-

- the licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for bona fide personal use;
- the quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner; and
- the licensing authority grants a permit in respect of the said drug in Form 12-B.

An import licence in Form 10 is required for import of drugs, excluding those specified in Schedule X and an import licence in Form 10-A is required for the import of drugs specified in Schedule X. For this an application for an import licence should be made to the licensing authority in Form 8 for drugs excluding those specified in Schedule X, and in Form 8-A for drugs specified in Schedule X, either by the manufacturer himself having a valid wholesale licence for sale or distribution of drugs, or by the manufacturer's agent in India either having a valid licence to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs and should be accompanied by the licence fee and an undertaking in Form 9 duly signed by or on behalf of the manufacturer. It should also be accompanied by a copy of Registration Certificate issued in Form 41.

The import licence and registration certificate is generally valid for a period of 3 years from the date of its issue.

An import licence will be subject to the following conditions:

(i) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;

(ii) the licensee shall allow any Inspector authorised by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substance and to take samples;

(iii) the licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;

(iv) if the licensing authority so directs the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under the last preceding sub-rule until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority;

(v) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter III of the Act, or the rules thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall the issues already made from that batch;

(vi) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the

licensing authority may specify and such record shall be open to the inspection of any Inspector authorised in that behalf by the licensing authority:

Provided that in respect of the sale or distribution of drugs specified in Schedule X, the licensee should maintain a separate record or register showing the following particulars, namely-

1. Name of the Drug,
2. Batch number,
3. Name and address of the manufacturer,
4. Date of transaction,
5. Opening stock on the business day,
6. Quantity of drug received, if any, and the source from which received,
7. Name of the purchaser, his address and licence number,
8. Balance quantity of drug at the end of the business day,
9. Signature of the person under whose supervision the drugs have been supplied.

(vii) the licensee shall comply with such further requirements, if any, applicable to the holders of import licenses, as may be specified in any Rules, subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than four months' notice.

No drug should be imported unless it is packed and labelled in conformity with the Rules in Parts IX and X and further conform to the standards laid down in Part XII provided that in the case of drugs intended for veterinary use, the packing and labelling shall conform to the rules in Parts IX and X and Schedule F(1) of the Drugs & Cosmetics Rules, 1945. No Homoeopathic medicine should be imported unless it is packed and labelled in conformity with the rules in Part IX-A.

Manufacture, sale and distribution of drugs and cosmetics

According to Sec.18, no person should himself or by any other person on his behalf –

a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute –
   i. any drug which is not of a standard quality, or is misbranded, adulterated or spurious;
   ii. any cosmetic which is not of a standard quality or is misbranded or spurious;
   iii. any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;
   iv. any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;
   v. any cosmetic containing any ingredient, which may render it unsafe or harmful for use under the directions, indicated or recommended;
   vi. any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made there under;
b) sell or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of the Act or any rule made there under;
c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued.

The provisions of this section will not apply to the manufacture of small quantities of any drug for the purpose of examination, test or analysis.

Procedure for obtaining Drug manufacturing licence

The Food and Drug Administration Department of the respective states is responsible for issuing manufacturing licences.

Approval of layout plan

- For Approval of Lay out Plan the Applicant has to submit 3 Blueprint copies of plan to the concerned Licensing Authority.(in case of Licenses for Blood Products and Vaccines Sera 4 Blue print copies of plan to be submitted)
- The plan should be as per the requirements prescribed for manufacturing premises in the Drugs and Cosmetics Act, 1940.
- The plan is scrutinized by panel of officers as per the requirements of the Drugs and Cosmetics Act, 1940.
- If necessary the premises is inspected by the concerned Inspector before plan Approval.
- Finally after scrutiny and compliance as per requirements of the Act the layout plan is approved and two copies are given to the Applicant.

Application for grant of Own Manufacturing Licence

The applicant has to make application in the requisite Form (24/24B/24C/27/27C/27D) and pay necessary fees as given in Appendix A. The following documents should be attached along with the application form –

- Receipt for the fees paid or challan as the case may be or their attested copies.
- Copy of Approved layout plan of the manufacturing area.
- Documents viz. Rent receipt, purchase documents or its attested copies showing lawful possession of the premises
- List of machinery and equipments.

- Documents relating to the constitution of the firm viz. Partnership-deed, memorandum and article of association etc.

- Full particulars of the competent technical staff employed for manufacturing and testing of drugs and cosmetics along with copies of their educational qualifications and experience certificates approval letter as competent staff. The competent technical staff is required to furnish consent letter for full time employment with the applicant firm.

- List of Drugs Cosmetics in triplicate along-with undertaking to be submitted.

- In case, the application is for the products covered under Schedule C and C (I) category, then the details of stability data is required.

- If the products are covered under 'Patent and Proprietary' definition, then the two copies of methods of Analysis of the products be supplied.

- Full name of the proprietor or the partners, as the case may be should be provided in the application. In case of private or public limited concerns, full name of the Directors who sign the application and the authorized signatory, if any, should be provided in the application.

The application is scrutinized and premises inspected.
If all conditions as prescribed under the Act are complied, then the licence is granted

Procedure for obtaining additional product permission

An application for permission to manufacture additional Drugs Products, Cosmetic Products should be made to the concerned Licensing Authority. The Covering letter of the application should mention all the details like firms expertise to manufacture the drug/cosmetics, manufacturing facilities etc. The following documents should be attached along with the application –

- List of products along with an undertaking in duplicate duly signed by the person In charge of Production, Managing Director, Owner, Partner or Director as the case may be.
- Stability data in Case of multivitamin products.
- In respect of a patent or proprietary drug product, information and therapeutic justification, indications, contra-indications, dosage schedule, availability of similar products in the market along with the method of analysis.
- In case of cosmetic additional product method of analysis and requisite BIS standard references.
- In case of Ayurvedic, Unani, Siddha product references regarding ingredients.
- Copy of cash receipt/challan showing the payment of prescribed fees.

The application is scrutinized and if required premises inspected.
If all conditions as prescribed under the Act are complied, then the licence is granted

Procedure for obtaining Drug selling licence

For the sale of Ayurvedic Drugs and Cosmetics no sale licence is required.

The Requirements of Sales premises are as follows –

Minimum carpet area:

- For Retail sale- 10 square meter
- For Wholesale- 10 square meter
- For Retail- Wholesale together - 15 square meter

Adequate storage facilities including cupboards with glass doors, racks refrigerator is required.

Application for grant of selling licence

The applicant has to make application in the requisite Form viz. 19/19A/19B/19AA and pay the necessary fees. The following documents should be attached along with the application form –

- Requisite Application Form.
- Receipt for the fees paid or challan, as the case may be or their attested copies.
- Layout plan of selling premises in 3 copies.
- Documents viz. rent receipt, purchase documents or its attested copies showing lawful possession of the premises.
- Documents relating to the constitution of the firm viz. Partnership-deed, memorandum and article of association etc.
- Full particulars of the competent technical staff /registered persons along with copies of their educational qualification, experience and registration certificates.
- Full name of the proprietor or the partners, as the case may be shall be provided in the application. In case of private or public limited concerns, full name of the Directors who sign the application and the authorised signatory, if any, shall be provided in the application.
- Documents for the purchase of Refrigerator/Deep freezer (For Vaccines / Sera).

The application is scrutinized and premises inspected.

If all conditions as prescribed under the Act are complied, then the licence is granted

Medical Devices

Medical Devices notified by the Government of India under the Drugs and Cosmetics Act, 1940 are regulated by CDSCO under the provisions of the Drugs and Cosmetics Rules, 1945. The manufacture of the notified devices is approved by the DCG(I) as Central License Approving Authority under the Drugs and Cosmetics Rules. Permissions are also granted for the conduct of clinical trial over medical devices in the country. Six Medical Devices Advisory Committees have been set up to review non-clinical as well as clinical trial data furnished by the applicants for the approval of marketing a new medical device in the country or to conduct clinical trial and give recommendation thereof.

Guidelines for import and manufacture of medical devices have also been issued.

Introduction of new drugs

Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials are prescribed under Schedule Y of the Drugs & Cosmetics Rules, 1945. Rules 122A to 122E i.e. Part XA also deals with the same. No new drug can be imported without the permission of the Licensing Authority. Approval to manufacture a new drug should be obtained from the Licensing Authority. Permission should be obtained from the Licensing Authority to conduct clinical trials for New Drug/Investigational new drug.

"New drug shall mean and include-

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration. (*See* items (b) and (c) of [Appendix VI] to Schedule Y.)

Explanation.- For the purpose of this rule–

(i) all vaccines shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;
(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier."

Clinical Trials

Under the Drugs and Cosmetics Rules, no clinical trials for a new drug, whether for clinical investigation or any clinical experiments shall be conducted except under, and in accordance with the permission granted by the Drugs Controller General (India). Clinical trials of pharmaceuticals products are conducted on human subjects to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics), and /or adverse effects with the object of determining their safety and /or efficacy. The protocols of such trials are examined by the office of DCG(I) before these permissions are granted.
Every approval / permission for conducting clinical trials also, inter alia, includes a condition that in case of study related injury or death, applicant will provide

complete medical care as well as compensation for the injury or death and statement to this effect should be incorporated in the informed consent form. Further in case of such injury or death the details of compensation provided should be intimated to the office of DCG (I).
Guidelines for conducting Clinical Trial inspection of site and sponsor / Clinical Research Organisations (CROs) are also available.

The **Clinical Trials Registry - India (CTRI)**, hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI).

Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient. Submission of Ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trialists are expected to regularly update the trial status or other aspects as the case may be. After a trial is registered, all updates and changes will be recorded and available for public display.

Being a Primary Register of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/), registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI (www.ctri.nic.in).

Important Schedules under the Drugs & Cosmetics Rules, 1945

1) **Schedule F** – deals with the requirements for the functioning and operation of a blood bank and / or for preparation of blood components.
2) **Schedule F(I)** – deals with provisions applicable to the production of vaccines.
3) **Schedule F (II)** – deals with the standards for surgical dressings
4) **Schedule F (III) -** deals with the standards for umbilical tapes
5) **Schedule FF** – deals with the standards for ophthalmic preparations
6) **Schedule J** – list of diseases and and ailments (by whatever name described) which a drug may not purport to prevent or cure or make claims to prevent or cure.
7) **Schedule M** – deals with good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products.
8) **Schedule M-I** – deals with requirements of factory premises for manufacture of Homeopathic preparations.
9) **Schedule M-II** – deals with requirements of factory premises for manufacture of cosmetics.
10) **Schedule M-III** – deals with requirements of factory premises for manufacture of medical devices.
11) **Schedule N -** list of minimum equipments for the efficient running of a pharmacy.
12) **Schedule O** – deals with standards for disinfectant fluids.

13) **Schedule T** – deals with good manufacturing practices for ayurvedic, siddha and unani medicines.

14) **Schedule U & U(I)** – particulars to be shown in manufacturing records.

15) **Schedule V** – deals with standards for patent or proprietary medicines.

16) **Schedule Y -** deals with requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials.

Offences and Punishment

Section	Offence	Punishment
13(a)	Import of adulterated/ spurious drug or cosmetic	Imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees
13(b)	Import of any other prohibited drug or cosmetic	Imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both
14	Import of adulterated/ spurious or prohibited drug or cosmetic	consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation

27(a)	Manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes adulterated/spurious drug	imprisonment for a term which shall not be less than ten years but which may extend to a term for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more
27(b)	Manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale, drugs without valid licence	Imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more
27(c)	Manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale any other spurious drug	Imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees or three times the value of the drugs

		confiscated, whichever is more
27(d)	Manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale any other drug not mentioned above	Imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than twenty thousand rupees
27-A	Manufacturers for sale or for distribution, or sells, or stocks or exhibits or offers for sale spurious/adulterated cosmetics	Imprisonment for a term, which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more.
28	Non-disclosure of the name of the manufacturer, etc.-	imprisonment which may extend to one year, or with fine which shall not be less than twenty thousand rupees, or with both
28-A	Not keeping documents etc., and for non-disclosure of information	Imprisonment which may extend to one year, or with fine which shall not be less than twenty thousand rupees, or with both
28B	Manufactures or sells or distributes any drug or cosmetic in contravention of the	Imprisonment for a term which may extend to three

	provisions of any notification issued under section 26A	years and shall also be liable to fine which may extend to five thousand rupees
29	Use of Government Analyst's report for advertising	Fine which may extend to five hundred rupees
33-I	Manufactures for sale or for distribution any Ayurvedic, Siddha or Unani drug deemed to be adulterated or without a valid licence	Imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more
33-I	Manufactures for sale or for distribution any Ayurvedic, Siddha or Unani drug deemed to be spurious	Imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more

2) Drugs (Prices Control) Order (DPCO), 1995

The drug prices in India are controlled by the Drugs (Prices Control) Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955 empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs, whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. The present Drug Price Control Order was passed on 6th January 1995.

Pricing of Bulk Drugs:

The 76 bulk drugs, the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. The methodology through which prices of DPCO-controlled bulk drugs are fixed is as follows. While fixing the maximum sale price of a bulk drug, the government has to provide either a post-tax return of 14% on net worth or a return of 22% on capital employed. Each company can choose one of the two methods mentioned above as per its own free will. So, the choice of method is company-specific and not product-specific. Then based on the chosen method, each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved. The government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers, before arriving at the final price. The price so decided will be binding on all manufacturers, irrespective of their actual cost of production.

Pricing of Formulations:

The Drug Price Control Order covers all the formulations that utilize the bulk drugs listed in the First Schedule. The methodology through which prices of formulations are fixed is as follows. Under DPCO 1995, a uniform MAPE (Maximum Aflowable Post-manufacturing expenses) of 100% is given on all formulations under price control. This is in contrast to the earlier practice of giving a MAPE of 75% on some formulations. In the new system, the retail price of a DPCO formulation is fixed equal to (MC+CC+PM+PC) x 2 + excise duty. It is this price that is printed on the pack of a DPCO controlled formulation. This price is not the Maximum Retail Price (MRP). Local taxes are additional. In order for the government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the government details of material cost, manufacturing process etc. The ceiling prices, once decided, are notified in the Official Gazette. For imported drugs and formulations, the landed cost including customs duty and clearing charges is the benchmark to fix prices. The margin allowed to the importer is such that selling and distribution expenses including interest and profit are covered. However, the margin allowed cannot exceed 50% of the landed cost.

3) The Pharmacy Act, 1948

In India there was no restriction to practise the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession. Hundreds of cases were brought to the notice of the Government wherein the compounding, mixing, or dispensing of medicines was being done by persons who were not adequately educated in this line. The system was causing great harm to the health of people by wrong compounding, mixing or dispensing. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. To achieve this goal the Pharmacy Bill, 1947 was

introduced in the Legislature which was later referred to the Select Committee. The recommendations of the Select Committee were incorporated in the Bill.

Object of the Act

It was desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practise the Profession of Pharmacy. It was accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for Pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. It was further proposed to empower Provincial Governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist.

Important provisions of the Act

The Pharmacy Act consists of 46 sections under 5 chapters. Most of the states in India have also enacted state specific Pharmacy Council Rules.

Chapter 1 – Introduction

Chapter 2 – Information about the Pharmacy Council of India

Chapter 3 – Information about State Pharmacy Councils

Chapter 4 – Procedure for registration of pharmacists

Chapter 5 - Miscellaneous

Registration of pharmacists

Registration of a pharmacist is done by the State Pharmacy Council constituted under section 19 of the Pharmacy Act.

According to Sec.32(2) of the Act, the minimum requirements for registration as a pharmacist are –

- Applicant should have attained the age of 18 years & paid the prescribed fee;
- Applicant should reside or carry on the business or profession of pharmacy in the state;
- Applicant should have successfully completed Diploma / Degree in Pharmacy from an Institution approved by the Pharmacy Council of India; or
- is a registered pharmacist in another state;

will be eligible for registration as a 'Registered Pharmacist'.

According to Section 42 of the Pharmacy Act no person other than a Registered Pharmacist should compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner and whosoever contravenes it will be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees or with both.

Powers of the State Pharmacy Council

Section 26A of the Pharmacy Act empowers the State Pharmacy Council, with the previous sanction of the State Government to appoint inspectors, who may -

a) Inspect any premises where drugs are compounded or dispensed;

b) Enquire whether a person who is engaged in compounding or dispensing of drugs is registered pharmacist;

c) Investigate any complaint made in writing in respect of any contravention of this Act;

d) Institute prosecution under the order of the Executive Committee of the State Council;

e) Exercise such other powers as may be necessary for carrying out the purposes of this Act or any rules made thereunder.

4) The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

An Act to control, the advertisement of drugs in certain cases, to prohibit the advertisement for certain purpose of remedies alleged to possess magic qualities and to provide for matters connected therewith.

The Act came into force on 1st April, 1955. It consists of 16 sections and one schedule. The schedule lists a number of diseases, disorders or conditions such as diabetes, cataract, cancer, fevers (in general), obesity, rheumatism, impotence, high or low blood pressure, female diseases, epilepsy, stature of persons, venereal diseases, glaucoma, sterility in women, dropsy, etc.

According to Act the Magic remedy includes a talisman mantra kavacha, and any other charm of any kind which is alleged and possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of human beings or animals.

Unless prescribed by registered medical practitioners or after consultation with the Drugs and Cosmetics Act 1940, no person or company, should take any part in the publication of any advertisement referring to any drug that is used for:

a) the miscarriage in woman or prevention of conception in women,

b) maintenance or improvement of the capacity of human beings for sexual pleasures,

c) correction of menstrual disorder in women, and

d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the Act.

No person or company should take part in advertisement which gives a false impression or makes a false claim for the drug or mislead the people. Whosoever contravenes any of the provision of this Act will be punishable with imprisonment extended to six months or with fine, or with both for first time conviction. It may extend to one year imprisonment or with fine or with both on subsequent convictions.

5) The Narcotic Drugs and Psychotropic Substances Act, 1985

The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha on 23 August 1985. It was passed by both the Houses of Parliament and it was assented by the President on 16 September 1985. It came into force on 14 November 1985.

This Act has 83 sections and one schedule giving the list of psychotropic substances. Substantive provisions of the Act are contained in chapter 3 dealing with prohibition, control and regulation of certain activities. These are reinforced by provisions relating to offenses and penalties in chapter 4.

Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, consume any narcotic drug or psychotropic substance. Narcotic drug means coca leaf, cannabis (hemp) opium straw and includes all manufactured drugs.

The Act is designed to fulfill India's treaty obligations under the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

The Act describes itself as "An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances, to provide for the

forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Convention on Narcotic Drugs and Psychotropic Substances and for matters connected therewith.

The Act provides power to the Central government to add to or omit the list of psychotropic substances, to take measures for preventing and combating abuse of and illicit traffic of narcotic drugs. There is a Consultative Committee to advise the Central Government for the implementation of this Act. The Narcotics Commissioner looks after the production of opium.

The cocca plant and cocca leaves can be used in the preparation of flavoring agents with the permission of central government.

No person should be engaged in or control any trade in which a narcotic drug or psychotropic substance is obtained from outside India and supplied to any person staying outside India.

Any officer of Gazette rank of the Department of Central Excise, Narcotics, Customs, Revenue intelligence or any other department of the Central Government or of the Border Security Force but superior in rank to a peon, sepoy, or a constable, is empowered to search, seize, or arrest any person who is engaged in dealing, sale, manufacturing narcotics, or psychotropic substances or helping other person for the same.

Any violation of the Act is punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees.

6) National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)

The National Pharmaceutical Pricing Policy (NPPP-2012) approved by the Cabinet on November 22, 2012 has been notified on December 7, 2012.

Price control over drugs was first introduced in the country in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These were promulgated under the Defence of India Act. With these orders, the prices of drugs were frozen w.e.f. the 1st April, 1963. Thereafter, a series of price control regimes were notified through various Orders in the country from time to time based on different principles, in which the span of control of prices as well as the nature of control of prices varied from Order to Order as per the disposition of the respective Drug Policies. These were the Drugs (Prices Control) Order of 1966, the Drugs (Prices Control) Order of 1970 - issued under the "Essential Commodities Act 1955 by declaring drugs to be essential commodities under the EC Act, 1955. Thereafter the Drugs (Prices Control) Order of 1979 and Drugs (Prices Control) Order, 1987 were issued following the declaration of Drug Policy, 1978 and Drug Policy 1986. All these Policies were broadly based on the principle of effecting control over prices of essential drugs and later bulk drugs, as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth cost effective production, innovation and strengthening of capacity.

The Drug Policy of 1994, as implemented through the Drugs (Prices Control) Order, 1995 was introduced in the context of the liberalization of economy and the abolishment of industrial licensing, as well as allowing of foreign investment in the country, including in the drug industry. The principle for price control broadly adopted in this policy represented a radical departure from the earlier policies. This envisaged control over prices of drugs on the basis of economic criteria as represented in the market share of different companies in the context of total market sales turnover of various drugs. Thus, those drugs were brought under the ambit of price control, where the company turnover was of a particular level and where the

market share of leading producers was beyond a particular level. The control over prices was to be on the basis of the cost of production with allowance being given for post production expenses. As per the criteria of 1994 Policy, a list of 74 bulk drugs was identified and these drugs as well as the formulations based on these drugs (currently about 1577 in number) were brought under the price control regime. Certain exceptions such as for small scale units, drugs produced through indigenous research and development, etc were envisaged for exemption under the Policy.

The Government felt that the Drug Policy, 1994 needs to be revised to meet the challenges brought about by the competitive international pharmaceutical industry in a globalised economic environment, as much as meeting the country's requirements for safe and quality medicines at reasonable prices. Therefore, the Government hereby enunciates the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which seeks to replace the Drug Policy enunciated in September, 1994 as "Modifications in Drug Policy, 1986" (Drug Policy 1994). The NPPP-2012 is in continuation of the Policy announced earlier in 1994.

The National Pharmaceuticals Pricing Policy 2012 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines (NLEM) – 2011 which was declared by the Ministry of Health and Family Welfare, Government of India vide communication No.12-01/essential medicines/08-DC/DFQC, dated 8th June, 2011.

The objective of the present policy is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.

The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are:

(1) Essentiality of Drugs

(2) Control of Formulations prices only

(3) Market Based Pricing

The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of essentiality of drugs. This is different from the economic criteria/market share principle adopted in the Drug Policy of 1994. The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations only. This is different from the earlier principle of regulating the prices of specified Bulk Drugs and their formulations adopted in the Drug Policy 1994. The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations through Market Based Pricing (MBP). This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy 1994.

The Ceiling Price (CP) will be fixed on the basis of readily monitorable Market Based Data (MBD) available with the pharmaceuticals market data specializing company – IMS Health (IMS). As the IMS data gives price figures for stockist level prices, in order to arrive at the CP (which will be the maximum retail price) the IMS price will be further increased by 16%.

Under the existing price control regime, the prices of Non-Scheduled drugs are monitored, and in case the prices of such drugs increase by more than 10% in a year, subject to certain criteria, government fixes the prices of such medicines from time to time. In the proposed policy, all essential drugs are under price control. It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months.

There will be no separate determination of Ceiling Prices for imported drugs falling under the span of control.

The prices of medicines which are a part of DPCO 1995 but not in NLEM-2011 would be frozen for one year and thereafter a maximum increase of 10% per annum, as in case of other non-NLEM medicines will be allowed.

There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

The CP for a drug listed in the NLEM would be the simple average of prices as calculated on the basis of IMS data six months prior to the date of announcement of the new National Pharmaceutical Pricing Policy ie the "Appointed Date" for bringing the new policy into effect. The prices of these NLEM-2011 medicines will be allowed an annual increase as per the Wholesale Price Index as notified by the Department of Industrial Policy & Promotion.

The prices of medicines which are a part of DPCO 1995 but not in NLEM-2011 would be frozen for one year and thereafter a maximum increase of 10% per annum, as in case of other non-NLEM medicines, will be allowed.

Indigenously developed and manufactured new drugs with patent (either process or product patent) and formulation involving a new delivery system developed through indigenous R&D would be eligible for exemption from price control for a period of 5 years.

Measures for strengthening of the pharmaceutical industry in the following areas –

(a) Strengthening and rationalizing the drug regulatory system.

(b) Bringing on a common platform all the regulatory authorities related to drug standards, bio-pharmaceuticals, clinical trials and Pharmacopeia.

(c) Promotion of research and development in the pharmaceutical sector, directly through research institutions and universities, as well as through provision of seed capital, venture capital funding and subsidies to innovative drug companies.

(d) Enablement of domestic pharmaceutical companies to achieve international GMP/GLP and GCP standards.

(e) Development of Human Resource, particularly in critical areas to meet the requirements of pharmaceutical industries.

(f) Rationalization of excise duties on pharmaceuticals.

(g) Setting up of common infrastructure through pharma development parks, pharma cluster schemes in order to strengthen and facilitate the smaller units in the pharmaceutical industries.

(h) Rationalization of pharma retail trade and strengthening of pharma supply chains.

A new Drugs (Price Control) Order would be notified as soon as possible after the Notification of the New Policy. The National Pharmaceuticals Pricing Authority will be the implementation authority for the new Policy and the new Drugs (Prices Control) Order. The NPPA would be provided required organizational and financial support so as to enable it to implement the new Policy in an effective, speedy and transparent manner. In due course, however, the DPCO, which is presently mandated under the Essential Commodities Act, would be replaced by specific legislation covering the issue of price control and monitoring of drugs, which would be fine tuned to the requirements of the drugs regulatory regime.

Important case laws

1) It is not necessary that the article should be applied to the whole body. If it is applied to a part of the body and if it beautifies or promotes attractiveness

oralters appearance then also it will be a cosmetic within the meaning of Drugs and Cosmetics Act, 1940; State of Bombay v. Zahid Hussain, 1975, Mah LJ. 455.

2) 'Gandh' and 'nail polish' are 'cosmetics' within the meaning of the Act; State of Bombay v. Zahid Hussain, 1975 Mah LJ 455

3) The definition of 'drugs' is an inclusive one. It includes all medicines for external or internal use of human beings or animals or any substances itended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals; Langamurti v.State of Orissa, (1973) I CWR 368

4) Water meant to be used for dissolving other medicines for injection into human body is 'drug'; R.C. Sundarka v. State of West bengal, 1971 Cr. LJ 1369: 77 CWN 437

5. RESEARCH AND DEVELOPMENT

Research & Development is the key to the future of pharmaceutical industry. The pharmaceutical advances for considerable improvement in life expectancy and health all over the world are the result of a steadily increasing investment in research. There is considerable scope for collaborative R & D in India. India can offer several strengths to the international R & D community. These strengths relate to availability of excellent scientific talents who can develop combinatorial chemistry, new synthetic molecules and plant derived candidate drugs.

The government has identified the pharmaceutical industry as one of the most important knowledge-based industries in which India has a comparative advantage. In order to turn India into a global R&D hub, the government has offered several R&D promotion measures to attract greater investment into the sector in order to update the existing technologies and to bring into the country technologies that were not yet available. In 1999, the Government set up the Pharmaceutical Research and Development Committee (PRDC) to study and identify the measures needed to strengthen the R&D base of the Indian pharmaceutical industry. The Committee recognized that priority must be given to initiating new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules, new delivery systems, and so forth.

Until the mid-1990s, R&D in the Indian pharmaceutical industry has focused on R&D for development of new processes for manufacturing drugs. Since that time, the new R&D focus is on the following four aspects: (1) new drug delivery systems (NDDS); (2) R&D for generic products for the regulated market and non-infringing processes; and (3) New drug Development Research (NDDR).

Indian companies are increasingly focusing on R&D for Nobel Drug Delivery System (NDDS). NDDS is the most vigorous R&S area where most of the top Indian companies are increasing investment. The leading pharmaceutical companies in India have

increased their R&D expenditures for development of generic products for the regulated market to satisfy quality and regulatory requirements for marketing off-patented drugs. Indian companies also have increased the development of non-infringing processes for filling Drug Master Fillings (DMFs) and Abbreviated New Drug Applications (ANDAs).

During the first quarter of 2011, Indian pharmaceutical companies filed 90 and total 271 Drug Master Fillings (DMFs) with US FDA during 2009 and 311 DMFs in 2010. In 2010, Indian pharmaceutical companies maintained their number one position in the US generics market, by bagging 33.17 per cent or 139 of 419 original Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA).

As supporters of TRIPS argued that the introduction of pharmaceutical product patent encouraged R&D for new drug development, Indian companies in the private sector began investing in R&D for New Drug Development Research (NDDR) in the mid-1990s. The leading Indian pharmaceutical companies are all now engaged in R&D for NCEs and have set up their own research centre for NDDR. Indian companies have reported some successes in NDDR. A number of new chemical entities (NCEs) have been developed which are at different stages of clinical trials.

The process of new drug development is classified into two stages: the pre-clinical stage and clinical stage. At the pre-clinical stage, the objective of research is to develop a promising molecule using animal models. At the clinical stage, the molecule is tested in humans and developed for manufacturing and marketing. About 40% of expenditure of new drug development goes to funding clinical development.

Recently, Contract Research and Manufacturing Services (CRAMS) business has been growing rapidly in India. CRAMS deals with manufacturing and research activities. Many Indian companies entered into CRAMS, and the number of the specialised CRAMS companies has increased. In post-TRIPS period, India is one of the most preferred outsourcing destinations for foreign pharmaceutical companies and is becoming a global manufacturing and R&D hub.

6. INTELLECTUAL PROPERTY RIGHTS

International property (IP) laws are both legal and business assets for pharmaceutical manufacturers.

Market protection has played a major role in the growth of the pharmaceutical industry. Pharmaceutical companies invest in years of research and development, expensive clinical trials and a lengthy regulatory approval process before their products ever reach the market. Intellectual Property laws are intended to give the investors an opportunity to recoup their costs.

Research-based companies that focus on new drug discovery, improving existing drugs, or developing new manufacturing processes or equipment to manufacture drugs rely on the patent system to recover their costs of development. Patent is a grant for an invention by the Government to the inventor in exchange for full disclosure of the invention. A patent is an exclusive right granted by law to applicants / assignees to make use of and exploit their inventions for a limited period of time (generally 20 years from filing). The patent holder has the legal right to exclude others from commercially exploiting his invention for the duration of this period. In return for exclusive rights, the applicant is obliged to disclose the invention to the public in a manner that enables others, skilled in the art, to replicate the invention. The patent system is designed to balance the interests of applicants / assignees (exclusive rights) and the interests of society (disclosure of invention). The procedure for granting patents, the requirements placed on the patentee and the extent of the exclusive rights vary widely between countries according to national laws and international agreements. In recent years the number of patent filings in India for pharmaceutical products has greatly increased.

Patentable invention is a new product or process, involving an inventive step and capable of being made or used in an industry. It means the invention to be patentable should be technical in nature and should meet the following criteria –

- Novelty: The matter disclosed in the specification is not published in India or elsewhere before the date of filing of the patent application in India.
- Inventive Step: The invention is not obvious to a person skilled in the art in the light of the prior publication/knowledge/ document.
- Industrially applicable: Invention should possess utility, so that it can be made or used in an industry.

TRIPs, the Agreement on Trade-Related Aspects of Intellectual Property Rights is an International treaty by the World Trade Organization (WTO) which sets down minimum standards for most forms of intellectual property (IP) regulation within all member countries of the World Trade Organization. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) treaty in 1994. After India signed the General Agreement on Trade and Tariff (GATT) and the Trade Related Aspects of Intellectual Property Rights Agreement, 1994 (TRIPS) and became a member of the World Trade Organization (WTO). As India is a signatory to the TRIPS Agreement and is a member of WTO, the Patents Act was amended in 2005 to make it confirm to these international agreements. Under Article 70(8)(9) of the TRIPS Agreement regarding pharmaceutical industry, India has the following obligations:

(a) To recognize in principle all kinds of inventions in the area of pharmaceutical and agricultural chemical products in accordance with Article 27 of the Agreement.

(b) To provide a mechanism by which applications can be filed for new inventions as understood in Article 27 in these areas from 1-1-1995.

(c) To apply the test of patentability as laid down in the Agreement irrespective of the law of the country on the date of filing, at the time when patent is granted or rejected.

(d) To provide patent protection for a period of 20 years, from the date of filing once the parties decide to grant the patent.

(e) In the case of product patent applications in these areas, grant exclusive marketing rights for five years or until patent is granted or rejected, whichever period is shorter.

Before the amendment of the Patents Act, 1970 in 2005, the Act expressly prohibited product patents and only permitted process patent. After the implementation of TRIPS, the Patents (Amendment) Act, 2005 gave way to product patents as well. The difference between process patent and product patent is that under a process patent, medicine or drugs which have been patented can be manufactured by another manufacturer but by using a different process. However, in a product patent drugs which have been patented cannot be manufactured by any process. Thus, product patent is a much stringent restriction than process patent.

Trade secrets are confidential business information which give a company a competitive edge or protects them from unfair competition. Pharmaceutical manufacturers protect their test data as a trade secret. It's a violation of law to disclose or gain unauthorized access to a trade secret. To be considered a trade secret, business information must be generally unknown, be of commercial value because of its secrecy, and the holder of the information must take reasonable means to keep the data secret.

A trademark, or brand, is a distinctive image, word or phrase that distinguishes a product or service from those produced by a competitor. In the pharmaceutical industry, trademarks may also be obtained for a distinctive colour or shape used in processing a drug tablet or capsule or on its packaging.

7. REGULATORY AUTHORITIES IN INDIA

Regulation of Pharmaceutical sector in India is divided between two ministries - The Ministry of Health & Family Welfare and the Ministry of Chemicals and Fertilisers of the Government of India. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy. However, other ministries also play a role in the regulation process. These include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology.

a) Department of Pharmaceuticals

The Department of Pharmaceuticals in the Ministry of Chemicals & Fertilizers was created on 01.07.2008 to provide greater focus for the growth of the Pharmaceuticals industry. The Ministry has been given the following mandate for catalyzing the growth of the pharma industry in the country -

- Drugs and Pharmaceuticals sector development
- Promotion and co-ordination of basic, applied and other research in areas related to the Pharmaceuticals sector.
- Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.
- Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- Promotion of public - private - partnership in pharmaceutical related areas.
- International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
- Technical support for dealing with national hazards in pharmaceutical sector.

- All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/monitoring.
- All matters relating to National Institutes for Pharmacy Education and Research.
- Supporting growth of Central Phama Public Sector Undertakings - BCPL, HAL, IDPL, KAPL and RDPL.

The work of the Department has been organized into three Divisions viz. Pharmaceuticals Industry Division, Public Sector Undertakings Division and R&D Division comprising National Institute of Pharmaceutical Education & Research, (NIPER) and Research & Development. The National Pharmaceuticals Pricing Authority (NPPA), an attached office of this Department, is entrusted with fixation and revision of prices of Pharmaceuticals products under Drug Price Control Order, 1995 (DPCO, 1995).

There are five Central Public Sector Undertakings (CPSUs) viz. Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and Pharmaceuticals Limited

(BCPL), Bengal Immunity Limited (BIL) and Smith Stanistreet Pharmaceuticals Limited(SSPL).

National Institutes of Pharmaceuticals Education & Research (NIPERs) is an autonomous institution under this Department.

b) Central Drugs Standard Control Organization (CDSCO)

The CDSCO has its head quarters at Food and Drug Administration (FDA) Bhawan, Kotla Road, Near ITO, New Delhi-110002. CDSCO has under its control Zonal / Sub-zonal offices, Port offices and Drugs Testing Laboratories to perform various regulatory functions in respect of quality control of drugs.

CDSCO has six zonal offices situated at Mumbai, Ghaziabad, Kolkata, Chennai, Ahmedabad and Hyderabad and four sub-zonal offices at Bangaluru, Chandigarh and

Jammu. The Port offices are situated at Mumbai (Sea and Airport), Nava Sheva (Sea Port), Kolkata (Sea and Airport), Chennai (Sea and Airport), Hyderabad (Airport), Delhi (Airport), Kochi (Sea Port) and Ahmedabad (Air Port) for exercising control over the quality of drugs, cosmetics and medical devices imported into the country.

CDSCO is discharging the following functions at its headquarters, zonal / sub-zonal offices, port offices –

- Grant of approval to manufacture and / or import new drugs and to conduct clinical trials with regulatory control as per provisions of the Drugs and Cosmetics Act and Rules.
- Approval of the licenses to manufacture certain categories of drugs as Central License Approving Authority (CLAA) i.e. Blood Banks, Large Volume Parenterals, Vaccines / Sera, r-DNA derived products, in-vitro diagnostic kits for detection of HIV1 & 2, HCV & HBsag and notified medical devices and its control as per provisions of the Drugs and Cosmetics Rules.
- Registration of foreign manufacturers of drugs and medical devices whose products are to be imported into the country and grant of licenses to import drugs and medical devices in the country and regulatory control over the quality of these products imported into the country.
- Grant of Test Licenses for import of drugs for the purpose of examination, test and analysis.
- Grant of licences to import drugs by Government hospitals or Medical Institutions for the use of their patients.
- Convening the meetings of Drugs Technical Advisory Board (DTAB) to discuss matter arising of the administration of the Act and recommended amendments to the Drugs and Cosmetics Rules.
- Convening the meetings of the Drugs Consultative Committee (DCC) to secure uniformity throughout the country in the administration of this Act.
- Recommend banning of drugs considered harmful or sub-therapeutic under section 26A drugs and Cosmetics Act.

- Conducting workshops and training programs in respect of various issues related to quality control of drugs.

c) National Pharmaceutical Pricing Authority

NPPA is an organization of the Government of India which was established, inter alia, to fix/ revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

The functions of the Authority are as follows –

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- to deal with all legal matters arising out of the decisions of the Authority;
- to monitor the availability of drugs, identify shortages, if any, and to take remedial steps;
- to collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations;
- to undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals;
- to recruit/ appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;
- to render advice to the Central Government on changes/ revisions in the drug policy;
- to render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

d) Indian Pharmacopoeia Commission (IPC)

This is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India.

The Commission has become fully operational from 1st January, 2009 as an Autonomous Body, fully financed by the Central Government with specific budgetary allocations under administrative control of the Ministry of Health and Family Welfare. The Secretary, Ministry of Health and Family Welfare, is the Chairperson and the Chairman-Scientific Body is the Co-Chairman of the Commission. The Secretary-cum-Scientific Director is the Chief Scientific and Executive Officer of the Commission.

IP prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP. IP standards are authoritative in nature. They are enforced by the Regulatory authorities for quality control of medicines in India. During Quality Assurance and at the time of dispute in the court of law the IP standards are legally acceptable. IP is an official document meant for overall Quality Control and Assurance of Pharmaceutical products marketed in India by way of contributing on their safety, efficacy and affordability.

The work of the IPC is performed in collaboration with members of the Scientific Body, subject experts as well as with representatives from Central Drugs Standard Control Organization (CDSCO), State Regulatory authorities, specialist from Industries, Associations, Councils and from other Scientific and Academic Institutions.

IP contains a collection of authoritative procedures of analysis and specifications for Drugs. The IP, or any part of it, has got legal status under the Second Schedule of the Drugs & Cosmetics Act, 1940 and Rules 1945 there under.

e) National Institute of Biologicals

National Institute of Biologicals an autonomous Institution under the Ministry of Health & Family Welfare (MOHFW)-Government of India is a premier Scientific Organization and a Centre of Excellence to ensure quality of biologicals and vaccines in the country.

The institute responsibly assures and reviews the quality of number of Biological products available through domestic manufacturers or imports. The operations are carried out in the state of the art Facility of the Institute and in close coordination with Government of India regulatory authorities as Office of Drug Controller of India, Indian Pharmacopeia's Commission.

With the current science and technology leading to the development of newer biologicals in the domestic market, the testing and specifications may vary for each specific products which requires an improved understanding of quality and safety issues.In recent years the licensing and quality control for manufacturer and National Regulatory Authorities alike has become even more complex. With this overall objective and to strengthen the regulations of biologicals in India, NIB, which is supported by the authorities, constituted of Governing body and General body of the Institute plays a vital role.

f) Narcotics Control Bureau, Government of India

The Government of India constituted the Narcotics Control Bureau on the 17th of March, 1986. The Bureau, subject to the supervision and control of the Central Government, is to exercise the powers and functions of the Central Government for taking measures with respect to:

- Co-ordination of actions by various offices, State Governments and other authorities under the N.D.P.S. Act, Customs Act, Drugs and Cosmetics Act and any other law for the time being in force in connection with the enforcement provisions of the NDPS Act, 1985.
- Implementation of the obligation in respect of counter measures against illicit traffic under the various international conventions and protocols that are in force at present or which may be ratified or acceded to by India in future.
- Assistance to concerned authorities in foreign countries and concerned international organisations to facilitate coordination and universal action for prevention and suppression of illicit traffic in these drugs and substances.
- Coordination of actions taken by the other concerned Ministries, Departments and Organizations in respect of matters relating to drug abuse.

The Narcotics Control Bureau is the apex coordinating agency. It also functions as an enforcement agency through its zones and sun-zones. Zones located at Ahmedabad, Bangaluru, Chandigarh, Chennai, Delhi, Guwahati, Indore, Jammu, Jodhpur, Kolkata, Lucknow, Mumbai, and Patna. Sub-zones located at Amritsar, Bhubaneswar, Dehradun, Goa, Hyderabad, Imphal, Madurai, Mandi, Nagpur, Raipur, Ranchi and Thiruvananthpuram. The zones and sub-zones collect and analyse data related to seizures of narcotic drugs and psychotropic substance, study trends, modus operandi, collect and disseminate intelligence and work in close cooperation with the Customs, State Police and other law enforcement agencies.

g) Pharmacy Council of India (PCI)

The PCI was constituted on 9.8.49 under section 3 of the Pharmacy Act.

The functions and duties of the Council are as follows –

- To prescribe minimum standard of education required for qualifying as a pharmacist.

- Framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy.
- To ensure uniform implementation of the educational standards throughout the country.
- Inspection of Pharmacy Institutions seeking approval under the Pharmacy Act to verify availability of the prescribed norms.
- To approve the course of study and examination for pharmacists i.e. approval of the academic training institutions providing pharmacy courses.
- To withdraw approval, if the approved course of study or an approved examination does not continue to be in conformity with the educational standards prescribed by the PCI.
- To approve qualifications granted outside the territories to which the Pharmacy Act extends i.e. the approval of foreign qualification.
- To maintain Central Register of Pharmacists.

LIST OF ADDRESSES OF STATE PHARMACY COUNCILS/ REGISTRATION TRIBUNALS

Sl.No	Name of the States Pharmacy Council / Tribunal	Tel. No.
1.	The Registrar, Andhra Pradesh Pharmacy Council, 2nd Floor, 21st Century Complex, Nampally, HYDERABAD-500 001 (A.P.)	0361-261865,281630,224196
2.	The Registrar, Assam Pharmacy Council,	

	C/o Dte.of Health Services, Dispur P.O., Hengrabari, GAUHATI-791 006 (Assam)	
3.	The Registrar, Bihar Pharmacy Council, B.M. Das Road, PATNA-800 004 (Bihar)	0612-2292220 09431060240
4.	The Registrar, Delhi Pharmacy Council, Room No. 198, Main Building, Old Secretariate, DELHI-110 054	011-23971285 , 23918440
5.	The Registrar, Gujarat State Pharmacy Council, Block No.0/4, New Mental Hospital, Complex Asarva, AHMEDABAD-380 016 (Gujarat)	079-22680060 , 26443984 **Website** : pharmacy-guj [at] nic.in
6.	The Registrar, Haryana State Pharmacy Council, S.C.F. 87, IInd Floor, Sector -4, PANCHKULA-134 112 (Haryana)	01684-240766
7.	The Registrar, Karnataka State Pharmacy Council, No.514/E, Ist Main, Vijayanagar Club Road,	

	R.P.C. Layout, Vijayanagar, 2nd Stage, BANGALORE-560 040 (Karnataka)	
8.	The Registrar, Kerala State Pharmacy Council, Pharmacy Bhavan, Public Health Laboratory Campus TRIRUVANANTHAPURAM-695 037 (Kerala)	**Tel No.** : 0471-470951 (O) **Fax No.**: 0471-572362 **Website** **:** www.pharmacycouncilkerala.org
9.	The Registrar, Maharashtra State Pharmacy Council, E.S.I.S. Hospital Compound, Lal Bahadur Shastry Marg, Mullund (West) MUMBAI-400 080 (Maharashtra)	022-5684291,5684418
10.	The Registrar, Orissa Pharmacy Council, C/o Dte. of Health Services, Nandankanan Road, BHUBANESHWAR-17 (Orissa)	481494
11.	The Registrar, Punjab Pharmacy Council, C/o Privar Kalyan Bhawan, Room No. 102-103, (Ground Floor), Sector 34-A, CHANDIGARH (U.T.)	01882-251506 0172-2661181

12.	The Registrar, Rajasthan Pharmacy Council, Sahkar Bhavan-22, Godown Circle Sardar Patel Dispensary Campus Sardar Patel Marg JAIPUR-302 006 (Rajasthan)	
13.	The Registrar, Tamil Nadu Pharmacy Council, Block-E, Ist Floor, Jawaharlal Nehru, Salai (100 feet), Inner Ring Road, Vadapalani, CHENNAI-600 026 (T.N.)	044-4728747 (O)
14.	The Registrar, U.P. Pharmacy Council, Flat No. 204, Arif Ashiana Building, Nibu Bagh Chowk, LUCKNOW-226 003 (U.P.)	0522- 2257518 , 2256570, 2264980
15.	The Registrar, West Bengal Pharmacy Council, 8, Lyons Range, (3rd floor), CALCUTTA-700 001 (W.B.)	2206454
16.	The Registrar/The Secretary (Health) Pharmacists Registration Tribunal, Admn.of Andaman & Nicobar Islands, C/o West Bengal Pharmacy Council, 8 Lyons Range, (Third floor)	

	CALCUTTA-700 001 (W.B.)	
17.	The Registrar, Chandigarh Pharmacy Council, General Hospital, Sector-16, CHANDIGARH-160 016 (U.T.)	
18.	The Registrar, Himachal Pradesh Pharmacy Council, S.D.A. Complex, Kusumpti, SHIMLA-171 009 (H.P.)	0177-221842, 221224, 221466
19.	The Registrar, Madhya Pradesh Pharmacy Council, J.P. Hospital Campus, P.O. Shivaji Nagar BHOPAL-462 001 (M.P.)	**Fax** : 0755-2764481
20.	The Registrar, Nagaland State Pharmacy Council Govt. of Nagaland Dte. of Medical Services, KOHIMA-797 001 (Nagaland)	0370-222263, 222626
21.	The Registrar, Pondicherry Pharmacy Council, Govt.Pharmacy Cahmpus, Indira Nagar,Gorimedu, Pudducherry 6	ponphacil@gmail.com

22.	The Registrar, Goa State Pharmacy Council Govt. of Goa C/o Directorate of Food & Drugs Administration D.B. Bandodkar Marg, PANAJI -GOA	
23.	The Registrar, Meghalaya Pharmacy Council, C/o Director of Health Services (MI), Health & F.W. Department, MEGHALAYA (Shillong)	94361-03924 09431-21292
24.	The Registrar-cum-Secretary, Mizoram Pharmacy Council, Directorate of Health Services, Mizoram, AIZAWL-796 001 (MIZORAM)	0389-2313694
25.	The Registrar/The Health Secretary, C/o Director of Health Services, Health & Medical Department, Govt. of Sikkim, GANGTOK-737 101 (Sikkim)	03592-24481
26.	The Registrar & Secretary, Tripura State Pharmacy Council, Health Directorate Building Gurkhabasti, P.O.-Kunjaban,	

	Agartala, TRIPURA-799 006	
27.	The Registrar/Health Secretary, Dadra & Nagar Haveli, C/o Director of Health Services, Health Department, Govt.of Dadra & Nagar Haveli & Daman & Diu, SILVASSA-396 230 (U.T.)	
28.	The Registrar/Health Secretary, Lakshadweep, C/o Director of Health Services, Health Department,Lakshadweep Admn., KAVARATTI-673 555 (U.T.)	
29.	The Registrar, Manipur Pharmacist Registration Tribunal, C/o Director of Health Services, Health Department, Govt. of Manipur, IMPHAL-795 001 (Manipur)	03852-2310263 , 2310768
30.	The Registrar/Chief Med.Officer, C/o Director of Health Services, Administration of Daman-Diu Collectorate, MOTI, DAMAN-DIU-396 220	0260-2230470 , 2230450

31.	The Registrar, Chattisgarh State Pharmacy Council Chhattisgarh State Pharmacy Council Quarter No. â€“77, Sector No.-3, Geetanjali Nagar RAIPUR (Chhattisgarh State)	098261-60000 09425570069
32.	The Registrar-cum-Secretary Registration Tribunal Pharmacy Govt. Pharmacy Institute, Variyatu RANCHI-834 009 (Jharkhand)	**Tel.No.** : 0651-2547044 **Fax** : 0651-2540467 09431371283 0651-2547044
33.	The Registrar, Uttaranchal Pharmacy Council M.L.H 107, Chander Nagar DEHRADUN-248 001 (Uttaranchal)	09412962384

8. REGULATORY AUTHORITIES AROUND THE WORLD

a) Food and Drug Administration (FDA)

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), and veterinary products.

The FDA has its headquarters in Silver Spring, Maryland. The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008, the FDA started opening offices in foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

b) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH)

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration.

The purpose of ICH is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines by recommending ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration. Harmonisation would lead to a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to

protect public health. ICH guidelines have been adopted as law in several countries, but are only used as guidance for the U.S. Food and Drug Administration.

c) European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products. From 1995 to 2004, the European Medicines Agency was known as European Agency for the Evaluation of Medicinal Products. Based in London, the EMA was born after more than seven years of negotiations among EU governments and replaced the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, though both of these were reborn as the core scientific advisory committees. Roughly parallel to the U.S. Food and Drug Administration(FDA), but without FDA-style centralization, the European Medicines Agency was set up in 1995 with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from member states, in an attempt to harmonize (but not replace) the work of existing national medicine regulatory bodies.

The European Medicines Agency operates as a decentralized scientific agency (as opposed to a regulatory authority) of the European Union and its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. More specifically, it coordinates the evaluation and monitoring of centrally authorized products and national referrals, developing technical guidance and providing scientific advice to sponsors. Its scope of operations is medicinal products for human and veterinary use including biologics and advanced therapies, and herbal medicinal products.

d) Therapeutic Goods Administration (TGA) (Australia)

The Therapeutic Goods Administration (TGA) is the regulatory body for therapeutic goods (including medicines, medical devices, gene technology, and blood products) in Australia. It is a Division of the Australian Department of Health and Ageing established under the *Therapeutic Goods Act 1989 (Cth)*. The TGA is responsible for conducting assessment and monitoring activities to ensure that

therapeutic goods available in Australia are of an acceptable standard and that access to therapeutic advances is in a timely manner.

e) Ministry of Health, Labour and Welfare (Japan)

The Ministry of Health, Labour and Welfare (*Kōsei-rōdō-shō*[?]) is a cabinet level ministry of the Japanese government. It is commonly known as*Kōrō-shō* in Japan. This ministry provides regulations on maximum residue limits for agricultural chemicals in foods, basic food and drug regulations, standards for foods, food additives, etc.

f) Medicines and Healthcare products Regulatory Agency (MHRA) (UK)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The agency was formed on 1 April 2003 with the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). It is an executive agency of the Department of Health. The roles of the MHRA –

1. Operate post-marketing surveillance for reporting, investigating and monitoring of adverse drug reactions to medicines and incidents with medical devices.
2. Assessment and authorisation of medicinal products for sale and supply in UK.
3. Oversee the Notified Bodies that ensure medical device manufacturers comply with regulatory requirements before putting devices on the market.
4. Operate a quality surveillance system to sample and test medicines to address quality defects and to monitor the safety and quality of unlicensed products.
5. Investigate internet sales and potential counterfeiting of medicines, and prosecute where necessary.
6. Regulate clinical trials of medicines and medical devices.
7. Monitor and ensure compliance with statutory obligations relating to medicines and medical devices.
8. Promote safe use of medicines and devices.
9. Manage the Clinical Practice Research Datalink and the British Pharmacopoeia.

9. INDUSTRY ASSOCIATIONS

List of Pharmaceutical associations in India and other countries –

a) **Indian Drug Manufacturers' Association (IDMA)**

www.idma-assn.org

Indian Drug Manufacturers' Association (IDMA), formed in 1961, works for Indian drug manufacturers' interests apart from protecting the interest of Indian consumer. It takes up policy issues related to implementation of the Drugs Cosmetics Rules with Central or State levels authorities. It has a membership of over 600 Indian pharmaceutical companies. It has many publications including IDMA Bulletin; Indian Drugs; IDMA Annual Publication; Indian Herbal Pharmacopoeia; IDMA-APA Forum - for professional Pharmaceutical Analysts; IDMA-PEG Newsletter - for Pharmaceutical Engineers; and Technical Monographs - Guidelines on standards in manufacture. IDMA has also instituted many awards for excellence in various fields of pharmaceuticals including patents, research and outstanding and young.
Contact Address: 102-B, Poonam Chambers, Dr.A.B.Road Worli, Mumbai - 400 018.

Phone: +91 - 22 - 2494 4624 / 2497 4308

Fax: +91 - 22 – 24950723

E mail: idma1@idmaindia.com, ppr@idmaindia.com

b) **The Organisation of Pharmaceutical Producers of India (OPPI)**

www.indiaoppi.com

The Organisation of Pharmaceutical Producers of India (OPPI) was established in 1965 as a premier association of research based international and large pharmaceutical companies in India. It is also a scientific and professional body. The mission of OPPI is to contribute towards achieving health care objectives of the nation while professionally addressing the collective interests of its members and encouraging

innovation for inclusive growth. It caters to the needs of Research based Pharmaceutical Industry. OPPI is an active member of International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Geneva. It has many publications including reports, codes, guidelines on pharmaceutical products and specific subject based publications like 'Outsourcing Opportunities in Indian Pharmaceutical Industry,' 'Corporate Social Responsibility of Pharmaceutical Companies in India' etc.

Contact Address: Peninsula Chambers, Ground Floor, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013.

Phone: +91 22 24918123, 24912486, 66627007

Fax: +91 22 24915168

E mail: indiaoppi@vsnl.com

c) **The Bulk Drug Manufacturers Association (BDMA)**

www.bdmai.org/index.html

The Bulk Drug Manufacturers Association (India), formed in 1991, is an all India body representing all the Bulk Drug Manufacturers of India. BDMA is a catalyst between the government and the industry on various issues for the growth of pharmaceutical drugs industry. It conducts periodical seminars on current technical topics; provides a platform for discussion among the member industries on various subjects concerning the Bulk Drug Industry; encourages innovations and make known the nature and merits of inventions; formulates methods for developing indigenous as well as export market for Bulk Drugs manufactured in India. BDMA publishes a monthly newsletter with information on day to day matters, articles from the eminent personalities, gadget notifications and other important information pertaining to pharmaceutical industry.

Contact Address: C-25, Industrial Estate, Sanath Nagar, Hyderabad 500018

Phone: 040 - 23703910/23706718

Fax: 040-23704804

E mail: info@bdmai.org

d) **The Confederation of Indian Pharmaceutical Industry (CIPI)**

www.cipi.in

The Confederation of Indian Pharmaceutical Industry (CIPI) is the apex body of small scale manufacturers of drugs and pharmaceuticals in India. Its federating members include all the major State level associations of the pharmaceutical manufacturers. The Confederation aims to bring together the members of Industry Associations into a body and to form a forum for representation to the Government or the other Public Authorities, Mercantile and Public bodies in India and elsewhere. It protects the general, commercial and business interest of the members and takes steps to advise them whenever required.

Contact Address: A-3/314, First Floor, Paschim Vihar, New Delhi – 110 063

Phone: 011-25275471

Fax: 011-28538801

E mail: admin@cipi.in

e) **Indian Pharmaceutical Association (IPA)**

www.ipapharma.org

Indian Pharmaceutical Association (IPA) is the professional association of pharmacists in India with a membership of over 10,000. It has 17 state branches and more than 33 local branches. It also manages several academic programmes and is affiliated with international pharma associations like FIP, FAPA, CPA, AAPS, AAiPS, IPSF & WHO. It has many important pharmaceutical publications to its credit including 'Indian Journal of Pharmaceutical Sciences' which is a bi-monthly scientific publication containing original research work in the areas of Pharmaceutical Sciences. It's another

publication; 'Pharma Times' is a news magazine and a scientific journal featuring articles of professional interest.

Contact Address: Kalina, Santacruz (E), Mumbai - 400 098.

Phone: 91-22-2667 1072

Fax: 91-22-2667 0744

E mail: ipacentre@ipapharma.org

f) **Association of Pharmaceutical Teachers of India**

www.aptiindia.org

Association of Pharmaceutical Teachers of India, established in 1966, aims at providing a common platform to discuss various issues of Pharmacy Education. Its objectives include identifying current needs of pharma industry and adapt the syllabus pattern as per the needs; honoring Pharmacy Educators and Researchers.; imparting Continuing Pharmacy Education (CPE); establishing a novel pharmacy teachers' training institute.; and arranging for lectures, exhibitions, etc, to focus on pharmacy profession through publications.

Contact Address: H.Q: Al-Ameen College of Pharmacy, Opp. Lalbagh Main gate, Hosur Main Road, Bangalore - 560027 INDIA

Phone: 080 – 22234619

Fax: 22225834
E mail: aptialerts@yahoo.com

g) **International Federation of Pharmaceutical Manufacturers Associations (IFPMA)**

www.ifpma.org

The IFPMA was founded in 1968 as a global, non-profit, non-governmental organization. With members across the world and a secretariat based in Geneva, Switzerland, the IFPMA represents the research-based pharmaceutical industry, including the biotechnology and vaccine sectors. Its members comprise 25 leading international companies and 45 national and regional industry associations covering developed and developing countries. Its primary role is to represent the members' views in dialogue with global intergovernmental organizations, the diplomatic missions of national governments and specialized non-governmental organizations.

The IFPMA advocates policies that encourage discovery of and access to life-saving and life-enhancing new medicines to improve the health of patients everywhere. To fulfill its mission, the IFPMA has established a number of key guiding principles:

- To encourage a global policy environment that is conducive to innovation in medicine, both therapeutic and preventive, for the benefit of patients around the world;
- To promote and support principles of ethical conduct and practices voluntarily agreed upon, as exemplified by the "IFPMA Code of Pharmaceutical Marketing Practices";
- To promote and support the adoption of high standards of manufacturing practices and quality assurance for pharmaceutical products;
- To contribute industry expertise and foster collaborative relationships and partnerships with international organizations that are dedicated to the improvement of public health, especially in developing and emerging countries; and

- To assure regular contact and experience-sharing and coordinate the efforts of its members towards achieving these objectives.

h) <u>European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)</u>

http://www.eucope.org/en

It is a trans-European Association for Pharmaceutical Entrepreneurs. Its goal is to support and to promote members of the pharmaceutical industry in all stages of the development of new products, including the fields:

- Scientific objectives
- Legal aspects
- Technical standards
- Economical possibilities

EUCOPE is active in the above mentioned areas:

- Transparent reimbursement and pricing decisions
- Fast national marketing authorisation procedures
- Incentives for incremental research
- Public perception of pharmaceutical innovations by SMEs
- Increased need for collaboration
- Community patent and strong intellectual property rights
- Recast of the clinical trials legislation
- Informed patient as political objective
- Effective promotion of R&D by tax incentives
- Reduced VAT rates for pharmaceuticals
- Prevention of late payment by public authorities

i) Drug Information Association (DIA)

www.diahome.org

The Drug Information Association (DIA) is a non-profit, worldwide association that aims to foster innovation, improve public health globally and provide a forum for knowledge exchange. It has over 23,000 members in more than eighty countries drawn from the discovery, development and management disciplines of pharmaceuticals and medical devices. The activities of the association are –

- Professional development through conferences and meetings.
- Training courses including in-company training, certificate programs and online training.
- Continuing education for healthcare professionals.
- Publications including drug information journals and magazines and a newsletter.
- Career guidance and job opportunities.

j) European Federation of Pharmaceutical Industries and Associations (EFPIA)

www.efpia.org

European Federation of Pharmaceutical Industries and Associations (EFPIA) is a Brussels-based trade union founded in 1978 representing the research-based pharmaceutical industry operating in Europe.

Through its direct membership of 31 national associations and 44 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,200 companies committed to researching, developing and bringing new medical treatments.

k) **European Pharmaceutical Market Research Association**

www.ephmra.org

The purpose of EphMRA is to develop and improve standards and techniques in Europe for market research in the field of health and healthcare, and to strengthen the role of the Association in the relevant decision-making processes in order to support its members in their international activities and to create transparency to the general benefit.

EphMRA assists its members to:

- Improve strategic decision-making throughout all member companies.
- Enhance the image of marketing research by improving techniques and methods in pharmaceutical marketing research and drives suppliers to provide cost effective solutions.
- Provide recognised standards by continuously supporting and actively participating in establishing high levels of standards and quality control in pharmaceutical marketing research.

l) **Pharmaceutical Business Intelligence and Research Group**

http://www.pbirg.com

The PBIRG is a not-for-profit industry association dedicated to the advancement of global healthcare marketing research, business intelligence, and strategic planning in theory and practice.

The objectives of the organization are:

- To promote and enhance the image of the marketing research, business intelligence, and strategic planning disciplines to –
    - provide guidance on ethical issues in marketing research and business intelligence

- communicate to management the value added by marketing research and business intelligence
- provide benchmarking input on job content and levels

- To provide education and training to enhance members' knowledge and skills by sponsoring meetings, workshops, and training sessions.

- To provide a forum to address industry issues

  - facilitate development of new databases
  - ensure quality control, standardization, and enhancement of current databases
  - conduct surveys on critical issues
  - provide input on marketing research certification

- To communicate/serve as liaison with
  - ethical pharmaceutical, biotechnology, diagnostic, and medical device companies
  - marketing research agencies
  - marketing research associations (e.g., EphMRA, PMRG, CPMRA, JP-MG)
  - industry/marketing associations (e.g., PhRMA, HBA, AMA)
  - other professional associations (e.g., SCIP, PDMA, PPDA)
- To provide input for other appropriate issues.

m) Japan Pharmaceutical Manufacturers Association

www.jpma.or.jp

The Japan Pharmaceutical Manufacturers Association or JPMA is the organization representing the research-based pharmaceutical industry operating in Japan.

n) Pharmaceutical Research and Manufacturers of America (PhRMA)

Pharmaceutical Research and Manufacturers of America (PhRMA) founded in 1958, is a trade group representing the pharmaceutical research and biopharmaceutical companies in the United States. PhRMA's stated mission is advocacy for public policies that encourage the discovery of new medicines for patients by pharmaceutical and biopharmaceutical research companies.

Its "mission is winning advocacy for public policies that encourage the discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical / biotechnology research companies. To accomplish this mission, PhRMA is dedicated to achieving in Washington, D.C., the states and the world.

- "Broad patient access to safe and effective medicines through a free market, without price controls,
- "Strong intellectual property incentives, and
- "Transparent, efficient, regulation and a free flow of information to patients."

10. IMPORTANT WEBSITES

www.mohfw.nic.in - Ministry of Health and Family Welfare, Government of India

http://www.pharmaceuticals.gov.in/ - Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers, Govt. of India

http://chemicals.nic.in/ - Ministry of Chemicals & Fertilisers, Govt. of India

http://cdsco.nic.in/ - Central Drugs Standard Control Organisations

http://indiaglp.gov.in/aboutNGCMA.html - National Good Laboratory Practice (GLP) Compliance Monitoring Authority

http://www.nppaindia.nic.in/index1.html - National Pharmaceutical Pricing Authority

www.pci.nic.in – Pharmacy Council of India

www.nihfw.org – National Institute of Health and Family Welfare

www.who.org - World Health Organization

www.iihmr.org - Indian Institute of Health Management Research

www.icmr.nic.in - Indian Council of Medical Research

http://www.dst.gov.in/scientific-programme/td-drugs.htm - Drugs & Pharmaceutical research, Department of Science & Technology

http://rdpp.csir.res.in/csir_acsir/Home.aspx - Council of Scientific & Industrial Research

http://ipc.nic.in – Indian Pharmacopoeia Commission (IPC)

http://nib.gov.in/ - National Institute of Biologicals

http://ctri.nic.in – Clinical Trials Registry – India

http://narcoticsindia.nic.in/ - Narcotics Control Bureau, Govt. of India

www.fip.org – International Pharmaceutical Federation

www.ich.org - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

About the Author

CA Rajkumar S. Adukia

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Mr. Rajkumar S Adukia is an eminent business consultant, academician, writer, and speaker. A senior partner of Adukia & Associates he has authored more than 34 books on a wide range of subjects. His books on IFRS namely, "Encyclopedia on IFRS (3000pages) and The Handbook on IFRS (1000 pages) has served number of professionals who are on the lookout for a practical guidance on IFRS. The book on "Professional Opportunities for Chartered Accountants" is a handy tool and ready referencer to all Chartered Accountants.

In addition to being a Chartered Accountant, Company Secretary, Cost Accountant,

MBA, Dip IFR (UK), Mr. Adukia also holds a Degree in Law and Diploma in Labor Laws. He has been involved in the activities of the Institute of Chartered Accountants of India (ICAI) since

1984 as a convenor of Kalbadevi CPE study circle. He was the Chairman of the Western Region of Institute of Chartered Accountants of India in

1997 and has been actively involved in various committees of ICAI. He became a member of the Central Council in 1998 and ever since he has worked tirelessly towards knowledge sharing, professional development and enhancing professional opportunities for members. He is a regular contributor to the various committees of the ICAI. He is currently the Chairman of Committee for Members in Industry and Internal Audit Standard Board of ICAI.

Mr. Adukia is a rank holder from Bombay University. He did his graduation from Sydenham College of Commerce & Economics. He received a Gold Medal for highest marks in Accountancy & Auditing in the Examination. He passed the Chartered

Accountancy with 1st Rank in Inter CA & 6th Rank in Final CA, and 3rd Rank in Final

Cost Accountancy Course in 1983. He started his practice as a Chartered Accountant on

1st July 1983, in the three decades following which he left no stone unturned, be it academic expertise or professional development. His level of knowledge, source of information, professional expertise spread across a wide range of subjects has made him a strong and sought after professional in every form of professional assignment.

He has been coordinating with various professional institutions, associations' universities, University Grants Commission and other educational institutions. Besides he has actively participated with accountability and standards-setting organizations in India and at the international level. He was a member of J.J. Irani committee which drafted Companies Bill 2008. He is also member of Secretarial Standards Board of ICSI.

He represented ASSOCHAM as member of Cost Accounting Standards Board of ICWAI.

He was a member of working group of Competition Commission of India, National

Housing Bank, NABARD, RBI, CBI etc. He has served on the Board of Directors in the capacity of independent director at BOI Asset management Co. Ltd, Bharat Sanchar Nigam Limited

and SBI Mutual Funds Management Pvt Ltd. He was also a member of the London Fraud Investigation Team.

Mr. Rajkumar Adukia specializes in IFRS, Enterprise Risk Management, Internal Audit,

Business Advisory and Planning, Commercial Law Compliance, XBRL, Labor Laws, Real Estate, Foreign Exchange Management, Insurance, Project Work, Carbon Credit, Taxation and Trusts. His clientele include large corporations, owner-managed companies, small manufacturers, service businesses, property management and construction, exporters and importers, and professionals. He has undertaken specific assignments on fraud investigation and reporting in the corporate sector and has developed background material on the same.

Based on his rich experience, he has written numerous articles on critical aspects of finance, accounting, auditing, taxation, valuation, public finance. His authoritative articles appear regularly in financial papers like Business India, Financial Express, Economic Times and other professional / business magazines. He has authored several accounting and auditing manuals. He has authored books on vast range of topics including IFRS, Internal Audit, Bank Audit, Green Audit, SEZ, CARO, PMLA, Antidumping, Income Tax Search, Survey and Seizure, Real Estate etc. His books are known for their practicality and for their proactive approaches to meeting practice needs.

Mr. Rajkumar is a frequent speaker on trade and finance at seminars and conferences organized by the Institute of Chartered Accountants of India, various Chambers of Commerce, Income Tax Offices and other Professional Associations. He has also lectured at the S.P. Jain Institute of Management, Intensive Coaching Classes for Inter & Final CA students and Direct Taxes Regional Training Institute of CBDT. He also develops and delivers short courses, seminars and workshops on changes and opportunities in trade and finance. He has extensive experience as a speaker, moderator and panelist at workshops and conferences held for both students and professionals both

nationally and internationally.. Mr. Adukia has delivered lectures abroad at forums of International Federation of Accountants and has travelled across countries for professional work.

Professional Association: Mr. Rajkumar S Adukia with his well chartered approach towards professional assignments has explored every possible opportunity in the fields of business and profession. Interested professionals are welcome to share their thoughts in this regard.