The word **Forensic** is derived from Latin term Forencis, meaning a forum, a place for interaction or deliberations. **Jurisprudence** means study of fundamental laws and in case of pharmaceutical Jurisprudence, it is laws relating to pharmacy.

Forensic Pharmacy or Pharmaceutical Jurisprudence is that branch of pharmacy, which deals with various legislations pertaining to drugs and pharmaceuticals, and profession of pharmacy. This subject encompasses the knowledge of various Acts, Rules, Statutes, Schedules, Sections etc., which directly or indirectly influence the profession of pharmacy in the country and various operations pertaining to procurement, manufacture and distribution of different kinds of dosage forms. Three important components of pharmacy profession – education, industry and pharmacy practice – are regulated by the pieces of legislation enacted from time to time.

The knowledge of Forensic Pharmacy is essential to understand the legal aspects pertaining to practice of pharmacy. The qualified persons are required to profess and should also be engaged in manufacturing, sales and distribution of drugs. Pharmacy is a noble and dedicated profession with a commitment to the cause of health care system of the country. In order to ensure this professional role of pharmacist, there has to be an ethical framework within which a pharmacist is supposed to function. He/she should be familiar with the types of laws governing his/her profession and also the developments that have contributed to the current status of pharma education, pharmacy practice and pharmaceutical industry.
Since ancient times, the human race has been depending upon the plant-derived drugs for the treatment of different human diseases. Apart from our own civilization, the Chinese, Greek, Arabian and Tibetan civilization have contributed significantly to the knowledge of medicinal plants. In our country Ayurveda, the Ancient Science of Life, based on ‘Tridosh’ theory of Vaat (wind), Pitta (bile) and Kapha (phlegm) is practiced from time immemorial. Our treatises or documents such as ‘Vedas’ and ‘Upanishads’ are full of information pertaining to medicinal plants. In ancient days, the medical care was in the able hands of ‘Maharshis’ and ‘Vaids’ who had a special status in the society. There was also the Siddha medicine mainly practiced in southern regions of the country.

With the advent of Moghul rulers specially Babur, there came in a new system of medicine practiced by Hakims called as Unani System of Medicine, which got patronage during the rule of Shahjahan and Aurangazeb. With the arrival of East India Company and other European companies and thereafter British rule in nineteenth century, the Indian population was first introduced to the Allopathic System of Medicine, more commonly known as “Vilayati Medicines”. The modern system of medicine was introduced in India by the Dutch, the French, the Portuguese and East India trading companies and the Missionaries from European countries.

Until the end of the nineteenth century, the medicines of different systems were mostly derived from plants or other natural sources like animals and minerals. These drugs were in the form of extracts, tinctures, pills and pastes and most of them were freshly prepared. The Ayurvedic medical practitioners were mostly hereditary and they were following Guru-Shishya parampara, which was also true of Siddha and Unani practitioners (Hakims). The Homoeopaths were self-taught and relied mostly on literature from Germany. In the absence of legal requirements of registration as doctor, a large number of quacks surfaced in medical profession.

The hospital facilities were almost non-existent in rural areas. The railway administration and plantations provided good services to their employees. The Missionaries and charity hospitals for communities were serving limited cause of health care.
**General Introduction**

In British India, the European establishments like Kemp and Company; Bliss and Cotton; and Frank Ross and Company were the important pharmacies. The Indian companies in British India were: Popular Pharmacy at Bombay; Dadha and Company, Wilfred Perira Ltd., and Appah and Company at Madras; H.C. Sen and Company and The Young Friends and Company at Delhi; Beli Ram and Brothers, The Punjab Medical Hall and Narayan Das Bhagwan Das and Company at Lahore; and Butto Kristo Paul and Company and M. Bhattacharya and Company at Calcutta.

There were no legally controlled systematic manufacturing efforts in the country for the manufacture of different drug formulations to be used for a longer period. It was only when plant drugs were further processed/purified, and synthetic as well as semi-synthetic compounds of medicinal utility were manufactured and formulated in different dosage forms, the need to enact laws to govern various operations of manufacture, sale and distribution was acutely felt.

**Current Status of Indian Pharmaceutical Industry**

Indian pharmaceutical industry has undergone rapid metamorphosis in last one decade. The post-GATT era was the testing time for strategic planning and development of indigenous pharmaceutical sector. The mergers and acquisitions have become the order of the day. India has become hub for clinical trials. Millions of dollars are being invested in basic and applied R & D efforts. Quality of medicines has become the keyword for global survival.

Today India’s position in world pharma market is 4th in terms of volume of medicines and 13th in value terms. Indian pharma companies are showing robust results and top ten Indian companies have recorded over 70% profits. There are around 24,000 manufacturing units, (large, medium and small scale) producing 90% requirement of medicines in the country. Currently, Indian companies produce about 22% of the world’s generic drugs. The total drug production has already crossed mark of ₹ 95,000 crores of which anti-infective and cardio vascular drugs account for 14.7% and 11.1% respectively.

India is one of the top five Active Pharmaceutical Ingredients (API) produce in the world today. The emergence of Indian pharmaceutical industry on global scenario as a strong generic player is due to Indian
Textbook of Forensic Pharmacy

Patents Act, 1970, which allowed only process patents. Although, India shifted to product patent regime in 2005, the capabilities developed earlier have provided an edge over many other developing countries especially, when rising healthcare costs in many developed countries forced them to seek the cheaper drug option. In 2011, more than a third of the ANDA (abbreviated new drug applications) approvals in the U.S. were from Indian firms. The formulation exports from India, essentially generic drugs have grown at 21% compounded annual growth rate (CAGR) between 2005-06 and 2010-11. Around 150 billion US dollars worth of drugs are set to loose patent exclusively between 2010 and 2015, which would provide further boost to export from India.

The Indian biopharmaceutical industry is fast growing and presently, it is sized at about US $ 1.8 billion. It is yet to make inroads in U.S. and Europe. The R & D capabilities of Indian pharmaceutical industry currently, lie in reverse engineering drugs and in process chemistry. Traditionally, Indian companies have shied away from drug discovery, or in a few cases, out-licensed molecules to multinational companies at early stage of development. At present, a limited number of Indian companies are engaged in new drug research and around eighty molecules are in pipeline from Indian players. For sustaining the growth, Indian pharmaceutical companies will be required to look at newer avenues such as building relationships with global pharma for joint R & D activities, entering niche segments and widening distribution networks through marketing alliances. Other potential thrust areas include contract research, biopharmaceuticals and new drug research. Since the average cost of developing a new drug has more than doubled in last five years amounting to approximately US $ 1.5 billion, strategic partnership for new drug research is the need of the hour.