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HISTORY OF PHARMACEUTICAL LEGISLATION

By
Mr. Sohansinh Vaghela
Assistant Professor
SIPS, Gandhinagar

Introduction

- The word *Forensic* is derived from Latin term *Forencis* means 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 branch of pharmacy, which **deals with various legislations** of drugs and pharmaceuticals and profession of pharmacy.
- This subject encompasses the knowledge of Acts, Rules, Statues, Schedules, Sections etc

Introduction

- **Ayurveda** (the Ancient Science of Life) based on '*Tridosh*' theory of *Vaat(wind)*, *Pitta* (bile) and *Kapha*(phlegm)
 - *documents such as 'Vedas' and 'Upanishadas'*.
- **Siddha** medicine mainly practiced in **southern regions** of the country.
- **Unani System:** **Moghul rulers** specially Babur, there came in a with new system of medicine practiced by Hakims
- **Allopathic System:** Come with **Britisher** in Nineteenth Century
 - *more commonly known as "Vilayati Medicines"*.

History of Drug Legislation

- During 1920-1930 there were number of reports of harmful substitutes and adulterants being marketed in place of genuine drugs and toxic effects of such drugs were observed.
 - *In place of eye drops, croton oil was used.*
 - *Chalk powder was frequently found to be used for adulteration of drug formulations.*
 - *There were toxicity due to overdose of mercury compounds.*

History of Drug Legislation

Drugs Enquiry Committee (D.E.C.):

- On 11th August, 1930, D.E.C. was constituted under the Chairmanship of **Col. R. N. Chopra** which was a historic development.
- **Terms of reference:**
 - *To find out **quality of drugs**, that are being imported, manufactured and sold especially, those which are official in B.P.*
 - *To suggest remedial measures for **checking** import, manufacturing, sale or distribution of the **substandard or spurious drugs** and their formulations.*
 - *To look into the formulations prepared indigenously from the vegetable drugs and suggest remedial measures for maintaining the **quality of such formulations**.*
 - *To look into all other **aspects** directly or indirectly connected with the **profession of pharmacy**.*

History of Drug Legislation

Report of Drugs Enquiry Committee (D.E.C.) (1931):

- There was **no systematic profession** like pharmacy being practiced in the country
- The drugs were dispensed and compounded by the **untrained people**
 - *The **remuneration** paid to them was **poor***
 - *They were also doing the work of dressers, helpers, laboratory technicians and all other **miscellaneous jobs** including, maintaining the accounts of doctors*
 - *These compounders were **able to read and write in English** and that was the only qualification they had for handling the drugs.*
 - *Only in the provinces of **Bengal and Madras**, there was a **training course** for compounders, chemists & druggists*

History of Drug Legislation

Recommendation of Drugs Enquiry Committee (D.E.C.):

- There should be **legislations to control** drugs and other remedies whether belonging to the B.P or not.
- There could be another **law** to ensure that drugs are **handled by qualified persons** and there could be a **systematic course in pharmacy**.
- A drug **regulating authority** at **center** and in **provinces/states** be established.
- There should be **drug/quality control laboratories** established in provinces and also at the centre.
 - *The efforts should be made to **publish Indian Pharmacopoeia**.*

History of Drug Legislation

Effect of Drugs Enquiry Committee (D.E.C.):

- In **1932**, Department of pharmaceuticals started by Banaras Hindu University.
- In **1935**, Indian pharmaceutical association in UP.
- In **1939**, Indian Journal of Pharmaceutical science
- In **1940**, All India Pharmaceutical conference organized by Indian pharmaceutical association
- In **1940**, The Drug Act, *later amended to The Drugs and Cosmetics Act, 1940*

History of Drug Legislation

The Health Survey and Development Committee, 1943

- Constituted under the Chairmanship of *Sir Joseph Bhore*
- Objective:
 - *Survey for the qualified and trained pharmacists and registration of pharmacists,*
 - *formation of Councils to govern the profession at Centre,*
 - *strengthening of the provisions of Drugs Act,*
 - *drug control laboratories for strengthening of infrastructure for drug regulation,*

History of Drug Legislation

The Health Survey and Development Committee, 1943

■ Recommendations:

- *Enactment of legislation* for qualified pharmacist and their profession
 - Foundation for the *Pharmacy Act, 1948.*
- *Establishment of All India Pharmacy council* – for regulate education
 - The Pharmacy Council of India was constituted in 1949
- *minimum qualification* for registration as pharmacist was prescribed and process for registration described.
- *regulate the advertisements* of drugs, which were in exaggerated form and misleading.
 - The Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954
- *Setting up of central drugs laboratory.*

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

■ PRE-INDEPENDENCE ERA

- **1664**, The **first hospital** was opened at Fort St. George, Madras.
- **1811**, Young Scotch named Mr. Bathgate came to India with East India Company and opened **Chemist's shop** in Calcutta.
- **1820**, Lord Cornwallis started **Opium factory** at Ghazipur (U.P.).
- **1824**, Hindustani versions (**Devnagri and persion scripts**) of the London Pharmacopoeia were prescribed.
- **1824**, The East India Company decided to **impart knowledge** of medical science-both European and Indian.
- **1835**, First **two medical** colleges established at Calcutta and Madras.
- **1857**, Few **sections of Indian Penal Code** were applicable for drugs.
- **1857, 1878**, **The Opium Act** enacted.
- **1860**, The beginning of **pharmaceutical instructions** in British India at Madras Medical College

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

■ PRE-INDEPENDENCE ERA

- **1885** **British Pharmacopoeia** was made the sole authority for pharmacy profession.
- **1889** The **Indian Merchandise Marks Act** enacted.
- **1894** The Indian **Tariff Act** enacted.
- **1898** **The Sea Customs Act**

enacted.

- **1899** The **Compounders training** course started in Madras.
- **1899** Achary P.c. Roy along with Kartic Chandra Bose established **Bengal Chemical and Pharmaceutical Works** at Calcutta.
- **1905** Gajjar and Co. established at Bombay which also started drug manufacturing.
- **1906** In **U.S.A. - Federal Food & Drugs Act** introduced.

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

- **PRE-INDEPENDENCE ERA**
- **1919** The **Poisons Act** enacted.
- **1920** All India Compounders and Dispensers Association was established.
- **9-3-1927** Resolution of Council of States in India regarding health services.
- **1928** The state medical faculty of Bengal introduced **two years course for compounders**.
- **11-8-1930** **Drugs Enquiry Committee** (D.E.C.) headed by Col. R. N. Chopra constituted.
- **1931** **Report** submitted by D.E.C.
- **1932** A two year Degree Course in Pharmaceutical Chemistry for B.Sc. - Beginning of pharmacy education at **BHU** by **Prof. Mahadev Lal Schroff** (**Father of Pharmacy Education in country**).
- **1-11-1933** The **Indian Medical Council Act** enacted.
- **1935** United Provinces Pharmaceutical Association (**UPPA**) established at Banaras by Prof. Mahadev Lal Schroff.

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

■ PRE-INDEPENDENCE ERA

- **1937** Biological Standardization Laboratory (**B.S.L.**) established at Calcutta.
- **1939** United Provinces Pharmaceutical Association (U.P.P.A) was **renamed** as Indian Pharmaceutical Association (**I.P.A.**). Publication of Indian Journal of pharmacy started.
- **1940** Drugs Bill introduced in the Parliament and Drugs Act later amended to **Drugs & Cosmetic Act**

(D.C.A) was enacted.

- **1940** Biological Standardization Laboratory was named as **Central Drugs Laboratory (CDL)** under DCA.
- **1941** First Drugs Technical Advisory Board (**DTAB**) constituted.
- **1941** **First All India Pharmaceutical Conference** was held at B.H.U, Varanasi under the Presidentship of **Prof. Mahadev Lal Schroff**.
- **1943** Health Survey and Development Committee constituted under the chairmanship of Sir **Justice Joseph Bhole**.

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

- PRE-INDEPENDENCE ERA
- 1944 First **I. P. Committee** constituted.
- 1945 Pharmacy Bill introduced in the Parliament.
- 1945 Justice Joseph Bhore submitted **report**.
- 1945 Rules for **Drugs & Cosmetic Act** framed.
- 1946 Indian Pharmaceutical Codex (**I.P.C**) published.

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

■ POST-INDEPENDENCE ERA

■ **1947** The **Indian Nursing Council Act** enacted.

■ **1948** The **Pharmacy Act, 1948** enacted.

■ **1948** The Dentists Act, 1948 enacted.

■ **9-11-1949** First '*Pharmacy Council Of India*' (**P.C.I.**) constituted under the Pharmacy Act.

■ **1949** **Dr. K.C.K.E. Raja** was nominated by the Central Government as the first President of Pharmacy Council of india.

■ **1951** The **Industries Act** enacted.

■ **11-7-1953** First Education Regulations (**E.R**) as approved by the Ministry of Health & F.W., Government of India were notified.

■ **1954** The **Drugs and Magic Remedies** (Objectionable Advertisements) Act enacted.

■ **1954** The first **B. Pharmacy** Course approved by Pharmacy Council of india at Birla College, Pilani.

■ **1955** The first **Diploma in Pharmacy** Course approved by P.C.I. at Government Medical College, Amritsar..

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

■ POST-INDEPENDENCE ERA

- 1955 **First IP** published.
- 1955 The Medicinal and Toilet Preparations (Excise Duties) Act.
- 1956 Essential Commodities Act enacted.
- 1956 The UGC Act enacted.
- 1957 Dangerous Drugs (Import, Export & Transshipment) Rules framed.

- 1960 Prevention of Cruelty to Animals Act passed.

- 1960-70 Indian Drugs & Pharma. Ltd. (I.D.P.L.) established at five places in the country.

- 1962 Beginning of National Pharmacy week celebrations in third week of November every year.

- 1963 Pharma Times Publication of I.P.A as professional monthly publication.

- 1963 The Indian Hospitals Pharmacists Association (IHPA) was launched at Pilani, Rajasthan.

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

- **POST-INDEPENDENCE ERA**
- **1966** Second IP published.
- **1968** Insecticides Act enacted.
- **1970** First DPCO (Drugs Price Control Order), Later on in 1979 and 1987, 1995 published.
- **1970** Indian Patents Act enacted.
- **1971** Medicinal Termination of Pregnancy Act enacted.
- **1972** Education Regulations of P.C.I. 1972 (notified on 6-1-1973).
- **1975** Hathi Committee Report Submitted. The Committee recommended that a Chief Pharmacist with at least a graduate in pharmacy degree should be appointed for maintaining quality of drugs supplied to patients in hospitals.
- **1975** All India Organisation of Chemists and Druggists (AIOCD) established with Mr. VL. Theagaraj as President.
- **1977** Indian Pharmaceutical Congress along with Conference of Commonwealth Pharmaceutical Association was held under the Presidentship of Dr. J.N. Banerjee at Mumbai

History of Drug Legislation

Important Milestones in Drug Legislations and Pharmacy Profession

- **POST-INDEPENDENCE ERA**
- **1978 Drug Policy** was announced based on Hathi Committee report.
- **1979** Indian Journal of pharmacy was named as **Indian Journal of Pharmaceutical Sciences** (Bi-monthly publication).
- **1985 Third Indian Pharmacopoeia** published.
- **1985** The **Narcotic-Drugs & Psychotropic Substances Act** enacted.
- **1986** Consumer Protection Act enacted.
- **1986 Revised Drug Policy** was announced.
- **23-12-1987** The All India Council for Technical Education (**AICTE**) Act covering pharmacy education enacted.
- **1989** Golden Jubilee of **Indian Pharmaceutical Association** celebrated.
- **2002 Pharmaceutical Policy** announced by Ministry of Chemicals and Fertilizers, Department of Chemicals.
- **2005** In Post-WTO era, new patent regime (**Product Patent**) has started.

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PHARMACEUTICAL ETHICS

Definition

- Ethics may be **defined as** “The code of moral principles or as the science of morals”
- **Law:** known as government control, while
- **Ethics:** known as Customs and duties of person.
- i.e.
 - *Law **prevent** from causing injury to another,*
 - *But law cannot force anyone to help neighbor in need.*
 - But this is the part of **morality principles/code of ethics**
- **Code of Pharmaceutical Ethics:**
 - *Contain Moral principles for pharmacist.*
 - *Ex. Selling of misbranded drug or adulterated drug is an offence, but it is immoral (unethical) also if pharmacist improve its sell by this.*

Code of Pharmaceutical Ethics

Code of conduct Classify as follows.

■ Pharmacist in relation to his job

- *Pharmaceutical services*
- *Conduct of Drug store*
- *Handling of prescription*
- *Handling of drug*

■ Pharmacist in relation to his trade:

- *Price structure*
- *Fair trade practice*
- *Purchase of drug*
- *Hawking of drug*
- *Advertising & Displays*

■ Pharmacist in relation to medical profession:

- *Limitation of professional activity*
- *Commission arrangements*
- *Liaison with public*

■ Pharmacist in relation to his profession

- *Professional vigilance*
- *Law abiding citizens*
- *Relation with professional organization*
- *Manners and properness*

Pharmacist's Oath

(As approved by the Pharmacy Council of India)

- I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team.
- I shall uphold the laws and standards governing my profession.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- I shall follow the system which I consider best for pharmaceutical care and counselling of patients.
- I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
- I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
- I shall associate with organizations having their objectives for betterment of the Profession of Pharmacy and make contribution to carry out the work of those organizations.
- While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of Pharmacy respected by all, at all times!
- Should I trespass and violate this oath, may the reverse be my lot!)

Pharmacy as a Career

■ Scope for diploma pharmacy (D. Pharm) students:

- *Community pharmacy*
- *Wholesale/Retail pharmacy*
- *Pharmacist in Hospital*
- *Lab technician in degree institute*
- *Higher education (B.Pharm)*
- *Marketing*

■ Scope for Degree pharmacy (B.Pharm) students:

- *Community pharmacy*
- *Wholesale/Retail pharmacy*
- *Pharmacist in Hospital*
- *Academics in D.Pharm*
- *Lab technician in degree institute*

- *Higher education (M.Pharm)*
- *Marketing*
- *Drug Inspector*
- *Industries*
 - *Production*
 - *R&D*
 - *Quality control*
 - *Quality Assurance*
 - *Packaging*
 - *Regulatory Affairs*
 - *Sale & Marketing*
- *Research*
- *Consultancy*
- *Abroad (work as pharmacist)*
- *Clinical research; etc.*