PHARMACEUTICAL LEGISLATION

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INTRODUCTION

- At the end of the 19th century and early 20 century use of Allopathy system increases
- Drugs of natural origin: Veg, mineral oil and animals
- At that time, profit became main motive than service
- Overdose of quinine
- Using croton oil in eye instead of atropine solution
- In adequate dispensing and selling
- Excellent dumping of drugs
- Drugs are badly adultered
- Instead of quinine, chalk tablets is used
- Drugs like satonine were badly adultered
- Potent drugs like antimony , arsenic and digitalis marketed without any standards
- Leading article published by Indian Medical Gazette (1927-1929)

"India become a land of quacks, of quacks doctors, quack medicine mongers, quacks dentists, quacks of medicines, quacks of opticians, quack of faith healers"

There was practically no legislation to control on drugs as well as on the pharmacy profession.

ORIGIN AND NATURE OF PHARMACEUTICAL LEGISLATION OF INDIA

- Earlier, the allopathic system of medicine was brought by Britisher's to our country and allopathic medicines were mainly imported
- To have some control on the import, the British Rulers introduced
- **The Indian Merchandise Marks Act 1889**
- **The Sea Customs Act 1898**
- **Indian Tariff Act 1894**
- **The Opium Act 1878**
- **Poison Act 1919**
- They were not comprehensive enough to control the chaotic and deplorable conditions in the drugs trade and industry.

DRUG ENQURY COMMITTEE

- On representation from the Indian people, the Viceroy appointed a committtee On 11th August,1930, under the chairmanship of Col. R.N. Chopra.

- So, this committee also called its viceroy committee/R.N.Chopra committee/Drug Enquiry committee.

- The report was published in 1931.
- The committee aspects were

ASPECTS

1) To enquire into the extent to which drugs and chemicals of impure quality or defective strength, particularly those recognized by the British Pharmacopoeia are imported, in the public interest, of controlling such importation, manufacture and sale and to make recommendations.

2) Recommendations to overcome the above.

3) The enquire into the necessity of legislation to restrict the profession of pharmacy to duly qualified persons and to make recommendations.

RECOMMENDATIONS

1) **A Central law** to control drugs and pharmacy profession.

2) **Setting up of test laboratories** in all states to control the quality of production of drugs and pharmaceuticals and a control laboratory to control the quality of imported drugs and also to act as expert referee in case of disputed samples sent by local Governments.

3) **Appointment of an Advisory Board** to advise the government in making rules to carry out the objects of the Act.

4) **Setting up of courses for training in pharmacy** minimum qualification for registration as a

6) **Registration of every patent** and proprietary medicines of undisclosed formula manufactured in India or imported from outside the country.

7) The crude single drugs as well as compounded medicines used in **indigenous system of treatment**, should be brought under control.

8) The **drugs industry in India should be developed**.

9) Gradual reduction of **manufacturing in Medical Stores Depots**.

10) **Compilation of an Indian pharmacopoeia .**

11) The **Cinchona Department** should cultivate Cinchona.

OUTCOMES OF THIS COMMITTEE'S REPORT (Central)

1. Enactment of **IMPORT OF DRUGS BILL 1937.**
2. **DRUGS AND COSMETIC ACT 1940 and Rules 1945.**
3. **PHARMACY ACT 1948**
4. **DRUGS AND MAGIC REMEDIES (Objectionable Advertisement) ACT, 1954 and Rules 1955.**
5. **MEDICINAL & TOILET PREPARATIONS (Excise Duties) Act, 1955 and Rules, 1956.**

6. Publications of first edition of INDIAN PHARMACOPOEIA in 1955 based on British pharmacopoeia 1948

- 1st Edition - 1955
- 2nd Edition - 1966
- 3rd Edition - 1988
- 4th Edition - 1996
- 5th Edition - 2007
- 6th Edition - 2014
- 7th Edition - 2018

STATE ACTS

- BENGAL: Bengal Municipal Act 1884
  Bengal Food Adulteration Act 1999
  Bengal Excise Act 1909
- MADRAS: Madras prevention of Adulteration Act 1919
- UTTARPRADESH: United Provinces Municipal Act 1916
- PUNJAB: Pure Food Act 1929
  Municipal Act 1911
- BIHAR AND ORISSA: Bihar and Orissa municipal Act 1922
  Prevention of Adulteration Act 1919
  Excise Act 1914

TYPES OF COMMITTEES

- BHORE committee
- BHATIA committee
- MUDALIAR committee
- HATHI committee

BHORE COMMITTEE

- October 1943---Health Survey and Development Committee – by Govt of India
- Chairman----Sir Joseph Bhore.

- COMMITTEE RECOMMENDATIONS:

- Establishment of an All India Pharmaceutical Council and provincial Pharmaceutical Council
- Strengthening of profession standards of pharmacists
- Maintaining disciplinary control
- Starting of revised courses of study
- Setting up of Central Drug Laboratory
- Rigid enforcement of the Drug and Cosmetics Act, 1940

BHATIA COMMITTEE

- Government of India in 1953---Appointed
- Pharmaceutical Enquiry Committee
- Chairman---Major-general S.L.Bhatia

- Made a comprehensive enquiry into the working of pharmaceutical industry.
- In June 1954, 212 recommendations have been implemented.

MUDALIAR COMMITTEE

- In 1959, Healthy Survey and Planning Committee appointed
- Chairman- DR.A. LAKSHMANSWAMY MUDALIAR

- Recommended the inclusion of indigenous systems of medicine under the purview of the Drugs Act.

HATHI COMMITTEE

- Important milestone in pharmaceutical legislation history is Hathi Committee
- Chairman- JAISUKH LAL HATHI

- This committee covered all the aspects of
- **Licensing, price control, imports, role of foreign sector quality control**.

REFERENCES

- A text book of **Forensic Pharmacy** – ***B.M.Methal***
- A text book of Pharmaceutical Jurisprudence &Ethics—***Dr.S.P.Agarwal & Dr. Rajesh Khanna***
- A test book of pharmaceutical Jurisprudence – ***K. Sampath***
- A test book of Forensic Pharmacy –***N.K. Jain***

THANK YOU