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Evolution of drugs VIS-A-VIS socio legal aspect: A historical perspective

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***Abstract*---**It is incredibly difficult to determine who developed the first medication. Perhaps stories have obscured the genesis and early history of medicine and drugs. The use of therapeutic herbs predates both human civilisation and ancient culture. Plants have played a key role in maintaining human health and well-being. The fact that the term Drug is derived from the French word drogue, which meaning dry herb, clearly implies that the first medicines were extracted from plants. Priority was given to plants over animal products and minerals in the treatment of illnesses by the earliest humans, who resorted to a variety of non-conventional techniques including plants, animal products, and minerals. Despite variances in their treatment concepts, the traditional medical systems of the world, such as Chinese Medicine, Ayurveda, and Greek Medicine, all agree that sickness is caused by an imbalance among the body's elements and that the goal of therapy is to restore the balance using herbs. Thus, plants were crucial in the evolution of pharmacology and pharmacy. The magnificent architect of modern-day sophisticated Pharmacology was not constructed overnight, but its basis was established on an ancient foundation. From its inception until the period of chemotherapy, pharmacology has travelled a great distance. In this article, the Pharmacology's journey is explained briefly.

***Keywords*---**Ayurveda, Drug, Medicine, Pharmacy, medical.

Introduction

Natural resources, mostly vegetables and plants, and their products, were used to make medicines in ancient India. In other cases, animal and mineral products were also utilised. Ayurveda was an Indian medical practise system. In comparison to today's medications, drugs were much less powerful back then. Their production, storage, and usage were not well-organized and scientific, and only a few specialised methods were used. Medicines were developed based on empirical ideas back then. For all of these reasons, there was no governmental oversight of medication production and distribution. In reality, such restrictions were unnecessary. (Dias, D. A., Urban, S., & Roessner, U. 2012, 330).

The current medical system (also known as allopathic medicine) was brought to India by British merchants who eventually became rulers in the late 1800s. During their reign, the British purposefully favoured the allopathic method. Initially, the allopathic or western style of medicine was primarily intended for the ruling elite, but by the end of the nineteenth century, it had gained popularity among the Indian people. The centrally legislated Drugs and Cosmetics Act, 1940 (DC Act) and the associated Drugs and Cosmetics Rules, 1945 govern the majority of drug regulation in India (DC Rules). However, since ‘public health' is a state issue under the Indian constitution, state governments have a significant amount of influence over drug regulation in the nation.

Drug management roles are changing in various nations as diverse approaches to health-care reform are adopted. Despite this, there is no evidence-based agreement on the effectiveness of drug management strategies. To determine the effectiveness of various treatments, a systematic review covering key areas of medication management is needed. Where effectiveness is unknown, the lack of it may inspire collaborative efforts to find evidence-based, cost-effective ways to improve medication management. The anticipated outcomes of this effort will be the establishment of evidence of what are known, allowing development aid partners and nations to concentrate on initiatives that have been shown to succeed. What is unknown is that a research agenda will be created to expand the body of information on effective pharmaceutical management interventions at the regulatory level, with developing nations having access to this expertise. (McAllister, W. B. 2002, 10)

The use of governmental power to establish and implement rules and standards in an effort to "manipulate pricing, quantities (and distribution), and product quality" is a basic wide definition of "regulation."

These kinds of legislative and administrative limitations are only completely effective in the context of a well-resourced regulatory structure, such as a well-functioning court system (for enforcement and punishment) and a well-resourced regulatory framework Changes at the level of a drug regulatory body typically need tough discussions since governmental regulation is essentially a product of the political process. For a number of reasons, governments control products and services. For example, the manufacture or consumption of some products may have an impact on other parties, either to their advantage or to their harm. In this scenario, governments opt to regulate by requiring producers and/or consumers

to consider these external consequences when making decisions. Furthermore, especially in the case of healthcare products or services, such as pharmaceuticals, bad economic choices are made because customers are unaware of all of their alternatives. Furthermore, government regulation is not free. In the worst-case scenario, adopting rules may raise prices and change behaviour in unexpected ways, resulting in unintended and negative effects.

The Knowledge of drugs is as old as man himself. From the dawn of civilization man has tried to find remedies against different ailments or diseases. The methods used rested, to a great extent, on psychical effects and certain simple procedures like bloodletting and cupping. However, attempts were also made to obtain efficient cure by drugs mainly by the vegetables and, to some degree, from animal and mineral kingdoms. Historical data shows that the drugs which are used in today's world were already prevalent in ancient times. The Babylonians, Egyptians, Greek, Romans, Chinese and Indians developed their own meteria, medica, a subject providing description of herbal and chemical drugs, their empirical use and dosage. (McAllister, W. B. 2002, 3)

To understand the history of medicines, we must first understand the history of pharmacology, which is derived from two Greek terms, "pharmakon" and "Logos," which respectively imply drugs and knowledge. Homer utilised it to make a medicine. When man first utilised a plant extract to alleviate the symptoms of an illness, the pharmacological idea was born. He must have deduced from his instincts that some plants had medicinal qualities. The majority of historians also believe that "neither empiricism nor magic stand at the beginning of men's internal use of medicines, but the animal function, the instinct!"

Drugs historical overview

Medica Materia Babylo-Assyriana Our understanding of early medicine in Babylonia and Assyria is limited. They were descendants of an ancient Sumerian civilisation. Their therapeusis was flavoured with water-related religious rites. R. Campbell Thompson, who studied hundreds of clay tablets from King Assurbanipal of Assyria's library in the British Museum, identified 250 vegetable medications and 120 mineral drugs. In certain cases, the medicines are grouped together, such as drugs for cardiac problems. In his renowned treatise on materia medica, the Greek Dioscorides mentions several of the minerals that the Assyrians knew and utilised (the first century after Christ).

Materia Medica in Egyptian and Greco-Roman times Ebers' papyrus, written about 1550 B.C. and found in Thebes in 1972 by George Moritz Ebers, contains the majority of our knowledge of ancient Egyptian therapeusis (1837-1898). There are 110 columns, each with 20-22 lines. More than 811 prescriptions and 700 medicines from the mineral, vegetable, and animal worlds are included. Overall, the Ebers papyrus demonstrates that Egyptian medicine had advanced to a high degree. It undoubtedly had a significant impact on Greek medicine, which we will now discuss. Therapeusis in early Greece was a modified form of Egyptian herbal polypharmacy, influenced by local beliefs in magical nature. Apollo was the mythic founder of the Greek rnaten medica. Herbal medicine eventually became intimately associated with Chiron the Centaur in the Greek hierarchy.

Hippocrates, the Father of Medicine (460-355 B.C.), a contemporary of Socrates, believed that nature's healing power was the most essential assistance in illness, and that medicines could only help the natural powers. Though he was familiar with man-made medicines from ancient Egypt and Greece, he seems to have utilised them sparingly, focusing instead on basic sanitary precautions (diet. fresh air, bath, and exercise). The materia medica' has not been updated in any way.

About 500 medicines were described by Theophrastus. Mistleloe, he said, was transmitted by birds, and he was the first to notice it. He created a picture of maddar and described its diuretic and analgesic effects. Celsus was an influential encyclopaedist who lived from 25 B.C. to 50 A.D. In the first volume of his work, "De medicina," he discusses medicines, many of which have made their way into contemporary pharmacopoeia. He placed a greater focus on meticulous nutritional control, but food delivered at the right time is his greatest medicine. Pedanius Dioscorides of Anazarba in Cilicia wrote a class work on medicines around the beginning of our era. He was a Greek physician in Nero's employ (54-68 A.D.). John Goodyer, a renowned botanist from Petersfield, translated the book between 1652 and 1655. On 4540 quarto pages, he wrote down the complete Greek text with an interlinear English translation. It was kept at Magdalen College, Oxford, for centuries until being printed in 1934 by R.T. Gunther, who added numerous Byzantine images. In 1902, however, a German version was published. Dioscorides' "De materia medica libri quinque" is a collection of five volumes in which the author describes nearly 900 medicines in detail. Some new medicines were introduced, including as copper and lead concoctions, as well as burnt chalk, for itching and astringent effects. The medicines and the concoctions made from them are described, along with suggestions for certain illnesses or disorders.

Galen (130-200 A.D.), who was born in Pergamom in Asia Minor, was a contemporary of Aretaeus. He did the most of his career as a physician in Rome. He was a prolific writer, having written over 400 books on various aspects of medicine. He has discussed a variety of medicines and their applications in his writings. He is the author of almost 30 books on the topic. "In order to know medicines, examine them not once or twice, but often," he suggested. "Narcotics are so supplied to me from Syria, Palestine, Egypt, Cappadocia, Pontus, Macedonia, Spain, Gual, and Africa," he says, in addition to the drugs he gathered himself.

Indian contribution

(a) Ayurvedic Materia Medica: Ayurvedic materia medica may be traced back to the Vedas, which were written approximately 5000 years ago. During the Vedic era, the Rig Veda and Atharva Veda were the primary sources of knowledge. The former includes sections extolling the therapeutic properties of plants and water, while the latter details a number of very effective medicines. The fact that doctors lived in cottages surrounded by gardens rich of herbs and medicinal plants suggests that a kind of materia medica existed back then. Charaka and Sushruta are the greatest authority in Indian medical history. Charaka distributes herbs to fifty groups, each of which is adequate for an average physician. (Chapter 4 of Cha. Sut.) Sushruta organised his materia medica into 37 sections based on the

illnesses that the medicines are intended to treat. Aconite, aloes, calamus, cannabis, cassia cassia fistula, crocus, curcuma, kamala, ricinus... are among the seven hundred sixty plants he mentions. Alum, arsenic arid, borax, cinnabaris, quicksilver, and zinc oxide were among his mineral medicines. He also included cantharides, moschus, viper meat, and different fats and excrements as animal drugs. In his work, Sushruta Samhita, he specifies the locations where certain herbs or, more precisely, simples might be located, as well as the best time to gather them. Poisons, apharodisiacs, and antidotes for different animal bites and stings seem to have piqued the Hindus' attention. The Sushruta Samhita's content was most likely taken from Greek sources. Other works exist in addition to Charaka's and Sushruta's traditional works. The Dhanvantari Nighantu seems to be the earliest Nighantu, with over 400 herbs mentioned. Bhava Mishra, a native of Banaras, wrote the Bhavapra-kash, a book on medicine that includes 600 medicines. Lala Shaligram, a Moradabad native, discussed carpets in his book " Shaligram Nighantu " 1574, some of which he illustrated with pictures. (Hakim Abdul Hameed, 1)

(b) Unani Materia Medica: In the 12th century A.D., the Greek materia medica was transferred to India. It flourished under the benevolent patronage of many Indian kings. When the doctors arrived in India, they used some of the finest and most effective Indian medicines and included them in their pharmacopoeia. Along with the conquerors, the Hakims first settled in Punjab, Delhi, and Sind. As a result, it began to take root in this nation under the reign of Alauddin Khilji (1290-1321A.D.).

Diya During his time at Tilang, Mohammad Masud Rashid Zangi, a courtier of Sultan Mohammad Tughlaq, authored the Persian novel Majmu-i-Diyai. It provides a comprehensive picture of the status of medicine in the Indian subcontinent. It covers Unani medications as well as Ayurvedic medicines and treatments. It is yet to be published. One copy of the Ms may be found at Jamia Hamdard's Central Library in New Delhi. Zayn ai-Din Ali (Jamal -al -Din) al-Hussain al- Ansari, also known as Haji Zayn al- Attar, was born in Shiraz in the year 730/1329. Sultan Shah Shuja (1364-84) died in 806/ 1403-4 after sixteen years of continuous service. Among his other works, he authored Miftah al-Khazain, a treatise on materia medica that was finished in 1366 and split into three maqalahs (i) on simple medicaments in alphabetical order (ii) on trading and enhancing them in alphabetical order (iii) on complex medicaments in twelve babs) (chapters). (Hakim Abdul Hameed, 1)

This book was updated and renamed Ikhtiyarat-Sadie in 770/1368-9, and it was dedicated to an unnamed princess Malikah Sadi al-Jarnat. It was split into two maqalahs: (i) simple medicaments in alphabetical order, and (ii) complex medicaments in sixteen babs (chapters). Ikhatyarat Qutb Shahi by Mir Mohammad Momin is an explanation and criticism of Ikhtiyarat Sadii, as well as a description of the investigator's viewpoints and the original sources of medicines. Hakim Mir Mohammad Hussain authored a thorough materia medica book. Makhzan al- Advia, a Persian book that has also been translated into Urdu, is his most renowned work. It contains about 1500 medicines. The majority are cultivated in India. On the margin of the piece is written Tuhfah al-Mominin.

Following the Sultanate era, the Mughals governed India, and the majority of Mughal emperors were supporters of learning. They promoted Unani medicine, which quickly spread throughout most of India.

Yusuf al-Harwi was the first and preeminent Tabib of the Mughal Emperor Babur's (1526-1530 A.D.) era, who authored a number of important treatises on medicine. He was a Herat native who arrived in India with his father, Mohammad b. Yusuf Harwi, in 1526 A.D. and was named the Emperor's head physician. Riyad alAdvia, a 1540 book dedicated to Humayun and written in alphabetical order, is the Hakim's greatest work on medicines. Its manuscripts may be found at the Khuda Baksh library in Patna, Bengal, the Maulana Azad library in Aligarh, the Salar Jung Museum in Hyderabad, and the British Museum. Hakim Ayn al-Mulk Shirazi (Dawai) dedicated a book to drugs, Fawaid al-Insan, written in 1595 A.D., during the reign of Akbar (1526-1606 A.D.). The basic medications have been listed alphabetically. Muzaffarb, another Hakim from the same era.

Mohammad al- Hussaini al- Sdfai (1628 A.D.) created the Shifa al-Atil pharmacopoeia, which has been recorded in history books under many titles such as Qarabadin Shifai, Qarabad-in Muzaffari, and so on. Hakim Amanullah Khan authored 'Ganj Bad Award' during Jahangir's reign (1605-1628 A.D.), which is an encyclopaedia of Unani medicines. The author cited 105 works written in Arabic, Persian, and Sanskrit. Shahjahan's era (1628-1658) had Hakim Nizamuddin Gilani (1586), a man of letters. The action and characteristics of basic medicines are the subject of his book "Khawass al-Advia." The State Central Library of Hyderabad has a copy of the Ms. Andhra Pradesh Oriental Manuscripts Library and Research Institute has now taken over the collection. Hakim Nural-Din Mohammad Abdullah, born in Agra, was another Hakim of the time who authored a large treatise on medicines called Alfaz al-Advia. It is an alphabetical list of simple and complex medicines, written in 1628 A.D. and dedicated to Shahjahan. In 1915, Hakim Najmul Ghani Khan, the son of Hakim Azam Khan's sister, published the massive book Khazinat al- Advia. Although it is based on the Muheet-e-Azam, it fills in certain gaps. There are 2612 medicines listed in it. Hakim Mohammad Sharif Khan (1725-1807 A.D.) is another notable physician who authored Talif-e-Sharifi, which deals with the effects and qualities of Indian medicines and foods, and (ii) 'laj al-Amrad, a pharmacopoeia that contains compound prescriptions based on illnesses. In 1879, it was published. The term 'Indian Materia Medica' was given to the English translation of the Persian original, which was published in Calcutta in 1833.

India's drug industry was virtually non-existent at the turn of the nineteenth century, and medicines were imported from outside. The First World War altered everything; not only were completed and low-cost medicines imported in greater quantities, but there was also a growing need for local goods from both sides. Manufacturing companies, both Indian and international, came up to manufacture medicines at lower prices to compete with imported items in response to the demand for Swadeshi goods. Naturally, some of them were of poor quality and potentially detrimental to the public's health.

As a result, the government was urged to take note of the issue and consider enacting laws to regulate the production, distribution, and sale of medications

and medicines. The Poisons Act and the Dangerous Drugs Act, respectively, were enacted in 1919 and 1930. The Opium Act was passed in 1878, and that was a long time ago. But, in order to have a comprehensive legislation, which the rapid expansion of the pharmaceutical production and market demanded by the end of the second decade for its control, the Indian Government appointed a Drug Enquiry Committee in 1931, chaired by Lt. Col. R.N. Chopra, to make shifting inquiries into the entire matter of drug production, distribution, and sale by inviting witnesses. In the interest of public health, the Committee was requested to provide suggestions on how to regulate the manufacture and distribution of medicines and pharmaceuticals.

The Chopra Committee travelled the country and, after carefully analysing the material presented to it, issued a lengthy report to the government proposing the establishment of a national drug control system with branches in all provinces. The committee also suggested the creation of a well-equipped Central Drugs Laboratory with qualified personnel and specialists in different fields for data modernization work in order for the controlling department to operate efficiently and quickly. It was proposed that local labs throughout the provinces would operate under the supervision of the Central Laboratory. The committee suggested that the Central Pharmacy Council and the Provincial Pharmacy Councils provide authorization for the training of young men and women pharmacists, with registrars maintaining records of licensed pharmacists' names and addresses.

The start of World War II in 1939 postponed the adoption of laws along the lines proposed by the Chopra Committee, which the Indian government deemed essential. However, in 1940, the Drugs Act was enacted, partially following Chopra's suggestions. The remainder of the necessary legislation were added to the Statute Book when the country gained independence in 1947. The Dangerous Drugs Act of 1930 and the Opium Act of 1873 were repealed by the Narcotics Drugs and Psychotropic Substances Act of 1985.

Legislations during the British Rule

The following are some of the laws that were in place in India throughout the 19th and early 20th century that had anything to do with medications and other therapeutic substances. Intentional adulteration of any medication in order to reduce its effectiveness, render it toxic, or alter its action is illegal under the Indian Penal Code (IPC). Only adulteration that makes a medication "noxious," "lessens its effectiveness," or "changes its action" is criminal under Indian Penal Code regulations. The Opium Act of 1978 controlled opium cultivation, production, possession, transportation, export, import, and sale. (Kumar, B. V., & Tewari, R. K. 1989, 12). The Indian Merchandise Act of 1889 dealt with the misbranding of products in general and the penalties for such violations. Customs tax is imposed on products such as pharmaceuticals, medicines, chemicals, and foods imported into or exported from India under the Indian Tariff Act 1894 and the Sea Customs Act 1898. The Poisons Act of 1919 was a simple piece of legislation that controlled the importation, possession, and sale of poisons. The Cantonment Act of 1924 gave cantonment officials the authority to enter any store and confiscate any ‘adulterated' medication or medicine.

Adulteration or contaminated drugs, on the other hand, lacked a clear description. (Sud, S., & Sud Khyati, S. 2016, 5). The Hazardous Substances Act of 1930 was passed to regulate the cultivation, manufacture, possession, import, export, transportation, and sale of dangerous drugs such as Coca, Hemp, and Opium. It included elements from the Opium Act of 1878. The Bengal Food Adulteration Act 1919, the Bengal Excise Act 1909, the Madras Prevention of Adulteration Act 1919, the Bombay Prevention of Adulteration Act 1925, the United Provinces (now Uttar Pradesh) Prevention of Adulteration Act 1912, and the Bihar and Orissa Prevention of Adulteration Act 1919 were just a few examples of state legislation. They all, however, avoided discussing the many regulatory issues of medicines and pharmaceuticals. (Sud, S., & Sud Khyati, S. 2016, 8)

Drugs Enquiry Committee

On August 11, 1930, the Indian government established the Drug Enquiry Committee, chaired by Col. R.N. Chopra, to investigate problems relating to the profession of pharmacy and its many elements in India. The 'Chopra Committee' was the name given to this Drug Enquiry Committee later on. The Committee's important terms of reference were: I to investigate the extent to which impure quality or defective strength drugs and chemicals, particularly those recognised by the British Pharmacopoeia, are imported, manufactured, or sold in British India, and to make necessary recommendations for controlling such activities in the public interest. ii) To report on how far and how broadly the aforementioned suggestions should be applied to pharmaceutical preparations employed in traditional medical systems. iii) To research and evaluate the need for legislation to limit the practise of pharmacy to properly qualified individuals, and to offer recommendations in this regard. With all of its seriousness and professional importance, the Chopra Committee took on the task of examining the issues and providing suggestions. They travelled to different parts of the nation to assess the situation. In 1931, the committee presented its report. In comparison to other areas of the globe, the committee report said that there was no organised and self-contained profession of pharmacy in India at the time. Compounders, a group of individuals who represent the profession, are ill-defined and misunderstood in terms of their position, roles, and responsibilities. They handle medicines and poisons with great ease and freedom, and in many instances, they are completely unaware of their qualities. The committee further noted that, with the exception of the updated compounder's course in Bengal and the Chemists and Druggists course in Madras from the late 1920s, little emphasis is placed on the fundamental qualification. To practise pharmacy, it was deemed sufficient to be able to read prescriptions written in English. The Medications Enquiry Committee also suggested that the Indian Pharmacopoeia be updated with monographs on commonly used drugs and medicines, including those of indigenous provenance. The Chopra Committee findings could not be implemented immediately by the Indian government. One of the main reasons for the Chopra Committee's recommendations not being implemented immediately was World War II. However, immediately after the committee's findings, pharmacy education in an organised and well-designed way began. In 1932, Prof. Mahadeva Lal Schroff established the first university-level pharmacy programme in India at Banaras Hindu University (BHU). Several more institutions followed suit and began

offering pharmacy programmes. With the help of Prof. Schroff, the United Provinces Pharmaceutical Association was founded in 1935 at BHU, and it eventually became the Indian Pharmaceutical Association (IPA). The professional journal "Indian and Eastern Chemist," which was initially published in London, began publishing in Calcutta as well. The Pharmaceutical Journal and the Chemist and Druggist of England have both come out in favour of the pharmacy profession's demand in India.

The Health Survey and Development Committee (Bhore Committee), chaired by Sir Joseph Bhore, released its findings in 1946. The Bhore Committee recommended that an enactment (Act) be passed with the goal of protecting the public's interests by increasing the interests of trained pharmacists. It was created when a committee discovered that inept individuals were handling medicines and causing damage to society. The Bhore Committee also recommended that the profession of pharmacy be reserved for pharmacists, and that pharmacists limit their activity to their profession's professional duties. It was also proposed that pharmacists should not be allowed to do tasks such as prescribing medications or administering anaesthetics. The committee also suggested that the country's pharmacy education be revised, since the current quality of training for individuals who want to practise pharmacy is inadequate. The Government of India introduced the Pharmacy Bill in 1945, based on the Chopra Committee's recommendations and the interim findings of the Bhore Committee, and it took the form of the Pharmacy Act 1948 after three years of constant efforts and debates at different levels. Under the terms of the Pharmacy Act, the first Pharmacy Council of India was established in 1949. The Pharmacy Act stipulated that the States must establish their Pharmacy Councils within three years of the Act's enactment, and the Education Regulations must be implemented within three years after that. As a result, the first Education Regulations under the Pharmacy Act should have been in effect in all Indian states by 1954, and individuals who are not certified to practise pharmacy according to the Education Regulations should not have been allowed to practise. The scenario, however, was different. The formation of Pharmacy Councils took a long period in many states. (Agarwal, N. B., & Karwa, M. 2018, 216). Even after the Pharmacy Act, the pharmacy profession has struggled to gain traction in the nation. In 1944, a committee was re-established under the leadership of Col. R.N. Chopra to compile information for a list of medicines used in India, regardless of whether or not they are included in the British Pharmacopoeia. Under the supervision of the aforementioned committee, the Indian Pharmacopoeial List, a precursor to the Indian Pharmacopoeia, was issued in 1946. A full-fledged Indian Pharmacopoeia Committee, chaired by Dr. B.N. Ghosh of Calcutta, was established in 1948, along with numerous sub-committees. The work took the committee seven years to accomplish, and the first edition of the Indian Pharmacopoeia was released in 1955. (Sangaonkar, R. E. 2017, 18)

Important Milestones in Drug Legislations

PRE-INDEPENDENCE ERA following Acts and Rules made there under that govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India: (Kumar, B. V., & Tewari, R. K. 1989).

1) 1664 The first hospital was opened at Fort St. George, Madras.

2) 1811 Young Scotch named Mr. Bathgate came to India with East India Company and opened Chemist's shop in Calcutta.

3) 1820 Lord Cornwallis started Opium factory at Ghazipur (U.P.).

4) 1824 Hindustani versions (Devnagri and persion scripts) of the London Pharmacopoeia were prescribed.

5) 1824 The East India Company decided to impart knowledge of medical science-both European and Indian.

6) 1835 First two medical colleges established at calcutta and Madras.

7) 1857 Few sections oflndian Penal Code were applicable for drugs.

8) 1857, 1878 The Opium Act enacted.

9) 1860 The beginning of pharmaceutical instructions in British India at Madras Medical College.

10) 1868 The Pharmacopoeia of India published under the authority of Secretary of State for India.

11) 1885 British Pharmacopoeia was made the sole authority for pharmacy profession.

12) 1889 The Indian Merchandi~e Marks Act enacted.

13) 1894 The Indian Tariff Act enacted.

14) 1898 The Sea Customs Act enacted.

15) 1899 The Compounders training course started in Madras.

16) 1899 Achary P.c. Roy along with Kartic Chandra Bose established Bengal Chemical and Pharmaceutical Works at Calcutta.

17) 1905 Gajjar and Co. established at Bombay which also started drug manufacturing.

18) 1906 In U.S.A. - Federal Food & Drugs Act introduced.

19) 1919 The Poisons Act enacted.

20) 1920 All India Compounders and Dispensers Association was established.

21) 1920 In Canada - Food and Drugs Act introduced.

22) 1924 The Cantonment Act enacted.

23) 1925 In U.K. - The Therapeutic Substance Act introduced. 9-3-1927 Resolution of Council of States in India regarding health services.

24) 1928 In U.K. Drug Adulteration Act enacted.

25) 1928 The state medical faculty of Bengal introduced two years course for compounders.

26) 1930 Drugs Enquiry Committee (D.E.C.) headed by Col. R. N. Chopra constituted.

27) 1931 Report submitted by D.E.C. to Central Government.

28) 1932 A two year Degree Course in Pharmaceutical Chemistry for B.Sc. - Beginning of pharmacy education at Banaras Hindu University by Prof. Mahadev Lal Schroff (Father of Pharmacy Education in country).

29) 1933 The Indian Medical Council Act enacted.

30) 1935 United Provinces Pharmaceutical Association (UPPA) established at Banaras by Prof. Mahadev Lal Schroff.

31) 1937 Import of Drugs Bill introduced in the Parli~ment (British India) and later withdrawn due to criticism.

32) 1937 Biological Standardization Laboratory (B.S.L.) established at Calcutta.

33) 1939 United Provinces Pharmaceutical Association (U.P.P.A) was renamed as Indian Pharmaceutical Association (I.P.A). Publication ofIndian Journal of pharmacy started.

34) 1940 Drugs Bill introduced in the Parliament and Drugs Act later amended to Drugs & Cosmetic Act (D.C.A) was enacted.

35) 1940 Biological Standardization Laboratory was named as Central Drugs Laboratory (COL) under DCA. 1941 First Drugs Technical Advisory Board (DTAB) constituted.

36) 1941 First All India Pharmaceutical Conference was held at B.H.U, Varanasi under the Presidentship of Prof. Mahadev Lal Schroff.

37) 1943 Health Survey and Development Committee constituted under the chairmanship of Sir Justice Joseph Bhore.

38) 1944 First I. P. Committee constituted.

39) 1945 Pharmacy Bill introduced in the Parliament.

40) 1945 Justice Joseph Bhore submitted report.

41) 1945 Rules for Drugs & Cosmetic Act framed.

42) 1946 Indian Pharmaceutical Codex (I.P.C) published.

Post-Independence Era

1) 1947 The Indian Nursing Council Act enacted.

2) 1948 The Pharmacy Act, 1948 enacted.

3) 1948 The Dentists Act, 1948 enacted.

4) 1949 First 'Pharmacy Council OJ India' (P.C.I.) constituted under the Pharmacy Act.

5) 1949 Dr. K.C.K.E. Raja was nominated by the Central Government as the first President of Pharmacy Counciiofindia.

6) 1951 The Industries Act enacted.

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

8) 1954 The Drugs and Magic Remedies (Objectionable Advertisements) Act enacted.

9) 1954 The Pharmaceutical Enquiry Committee recommended appointment of graduates in Pharmacy as Chief Pharmacists for all large hospitals.

10) 1954 The first B. Pharmacy Course approved by Pharmacy Council ofindia at Birla College, Pilani. 1955 The first Diploma in Pharmacy Course approved by P.C.I. at Government Medical College, Amritsar.

11) 1955 First Indian Pharmacopoeia published.

12) 1955 The Medicinal and Toilet Preparations (Excise Duties) Act.

13) 1956 Essential Commodities Act enacted.

14) 1956 The University Grants Commission Act enacted.

15) 1957 Dangerous Drugs (Import, Export & Transshipment) Rules framed.

16) 1960 Prevention of Cruelty to Animals Act passed.

17) 1960-70 Indian Drugs & Pharmaceuticals Ltd. (I.D.P.L.) established at five places in the country.

18) 1962 The Central Manufactured Drugs Rules framed.

19) 1962 Beginning of National Pharmacy week celebrations in third week of November every year.

20) 1963 Pharma Times Publication of I.P.A as professional monthly publication.

21) 1963 The Indian Hospitals Pharmacists Association (IHPA) was launched at Pilani, Rajasthan.

22) 1964 The Indian Journal of Hospitals Pharmacy was started by Prof. B.D. Miglani for IHPA.

23) 1966 Second Indian Pharmacopoeia published.

24) 1968 Insecticides Act enacted.

25) 1970 First DPCO (Drugs Price Control Order), Later on in 1979 and 1987, 1995 published.

26) 1970 Indian Patents Act enacted.

27) 1971 Medicinal Termination of Pregnancy Act enacted.

28) 1972 Education Regulations of P.C.I. 1972 (notified on 6-1-1973).

29) 1973 Homoeopathy Central Council Act enacted.

30) 1974 Committee of M.P.s with Jaisukhlal Hathi as chairman for drugs and pharmaceuticals constituted.

31) 1975 Hathi Committee Report Submitted. The Committee recommended that a Chief Pharmacist with atleast a graduate in pharmacy degree should be appointed for maintaining quality of drugs supplied to patients in hospitals.

32) 1975 All India Organisations of Chemists and Druggists (AIOCD) established with Mr. VL. Theagaraj as President.

33) 1976 The Dentists (Code of Ethics) Regulations framed.

34) 1977 Indian Pharmaceutical Congress along with Conference of Commonwealth Pharmaceutical Association was held under the Presidentship of Dr. J.N. Banerjee at Mumbai.

35) 1978 Drug Policy was announced based on Hathi Committee report.

36) 1979 Indian Journal of pharmacy was named as Indian Journal of Pharmaceutical Sciences (Bi-monthly publication). 1981 Education Regulations ofP.C.I. notified on 11.7.1992.

37) 1985 Third Indian Pharmacopoeia published. 1985 The Narcotic-Drugs & Psychotropic Substances Act enacted.

38) 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.

39) 1989 Golden Jubilee of Indian Pharmaceutical Association celebrated.

40) 1991 Education Regulations ofP.C.1. Notified in 1993.

41) 1994 Modifications in Drug Policy, 1994.

42) 1996 Hon. Supreme Court directed Government to come out with National Policy on Blood Programme. Subsequently, National Blood Policy of NACO (National AIDS Control Organization) brought out.

43) 1998 Golden Jubilee of Indian Pharmaceutical Congress along with Conference of Federation of Asian Pharmaceutical Association (FAPA) was held at Mumbai under the president ship of Prof. C.K. Kokate.

44) 1999 Golden Jubilee Year of Pharmacy Council of India celebrated throughout the country.

45) 2001 The first pharmacist (Prof. C.K. Kokate) appointed as Vice-Chancellor of Indian University, (Kakatiya University A.P.).

46) 2002 Pharmaceutical Policy announced by Ministry of Chemicals and Fertilizers, Department of Chemicals.

47) 2005 In Post-WTO era, new patent regime (Product Patent) has started.

Conclusion

This chapter attempted to understand how drug regulation works in India through the ancient time period to present. Drug regulation in India is a complicated process overseen by several ministries, notably the Ministry of Health and Family Welfare, and governed by legislation, namely the Drugs and Cosmetics Act of 1940. At both the federal and state levels, the legislation establishes a network of regulatory agencies to oversee the process. The Drugs and Cosmetics Act of 1940 established the Central Drugs Standard Control Organisation (CDSCO), within which the Drugs Controller General of India (DCGI) serves as the primary regulatory authority, acting on the advice of the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). CDSCO is organised into zone offices that are located across the nation and have specific responsibilities in drug control, including as inspections, recalls, and market monitoring. CDSCO is also responsible for supervising the operation of state drug-control agencies. State Drug Regulatory Authorities (SDRAs) are statutory organisations established under the Drugs and Cosmetics Act of 1940 at the state

level. SDRAs are charged with certain elements of drug regulation and fall under the jurisdiction of each state's Health Department.

In reality, CDSCO handles policy-making and permits for manufacturing and licencing, while SDRAs seem to manage some implementation under CDSCO's supervision. SDRAs are often merged with the state's food regulation agency under the Food and Drug Administration (FDA), which makes it difficult to distinguish between regulatory duties and adds to administrative complexity. The SDRAs use a team of drug inspectors to keep an eye on the quality of medicines and medical equipment being produced, as well as the standards that govern where they are sold. State licencing agencies control licencing of sale and production facilities within their jurisdiction, but only the central licencing authority may approve new medicines.

The Indian medicine market is unusual in many ways: it is dominated by branded generics, and it is characterised by large volume and cheap price. This is in addition to the fact that the Indian market has the potential for exponential expansion and is already showing indications of doing so. 1 A growing middle class with rising disposable incomes, better access to medical facilities, and more knowledge of (and access to) health insurance are all factors that have aided the pharmaceutical industry's development. The regulatory difficulties have changed as the pharmaceutical sector has expanded in response to the changing environment. This raises the issue of whether India's regulatory structure has been able to adapt to shifting market demands.

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