Principle Authorities Supervising India's Pharmaceutical Landscape

[1]S. Subash , [2]K. Kathiresan

[1]PG student, Department of Pharmacy, Annamalai University, Chidambaram.

[2]Associate Professor, Department of Pharmacy, Annamalai University, Chidambaram.

Email: ss.subash99@gmail.com

Email: dr.kathiresan123@rediffmail.com

Abstract

This article aims to explore the regulatory bodies that regulate the pharmaceutical sector in India. This article also highlights the role and goals of regulatory bodies in the pharmaceutical sector. The main aim of this article is to highlight the effective participation of regulatory bodies and authorities in assuring the well-being, quality, and effectiveness of drugs in the Indian market The findings revealed that the Central Drug Standard Control Organization (CDSCO), Indian Council of Medical Research (ICMR), National Pharmaceutical Pricing Authority (NPPA), and Indian Pharmacopoeia Commission (IPC) play crucial roles in drug approval, quality control, pricing regulation, and setting quality standards. This study implies that these regulatory bodies collectively work to maintain high-quality standards and regulate the industry to safeguard public health and ensure the availability of safe and effective medicine [1]

Keywords: *CDSCO, ICMR, NPPA, and IPC.*

1. Introduction

The manufacturing industries of drugs in India were in the developing stages until the 20th century. Major quantities of drugs are traded in countries such as China. Imported drugs include Metformin, Ranitidine, Ciprofloxacin, Metronidazole, Ibuprofen, and many more. Following World War I, the requirement for drugs significantly increased, which led to the manufacture of low or poor-quality and inauthentic drugs in India [1]. In India pharmaceutical goods are regulated by the Drugs and Cosmetics Act, 1940 and Rules 1945 [2]. Pharmaceutical regulations are defined as "a combination of lawful, administrative, and technical measures that governments take to ensure the well-being, effectiveness, and quality of drugs, as well as the relevance and accuracy of product information [3]. The drug regulatory authority is "the agency that is responsible for development and implementing the pharmaceutical regulation in the country [3].

[1] S.Subash

The Indian pharmaceutical sector is a largely regulated industry, governed by several major bodies that aim to ensure the well-being, quality, and effectiveness of drugs. These regulatory bodies play a pivotal role in securing the interests of consumers and pharmaceutical companies. In this study, we explore the important organizations that regulate the Indian pharmaceutical sector [4].

2. Pharmaceutical Regulations Goals

The WHO provides and explains the pharmaceutical regulations goals, which were reported in the year 2003.

1. Development and Implementation of most regulations on pharmaceuticals that focus on assuring the well-being, quality, and effectiveness of medicinal products.
2. Provision of accurate drug product information.
3. Development of legislature for the pharmaceutical product.
4. To preserve and safeguard the patient from life-threatening, hazardous, and/or misbranded drugs and medications. [3]

Main causes for regulations of drugs:

● Abuse of drugs, such as Antibiotics might lead to serious health issues and also might lead to a lethal state for both individual as well as public health.

● Existence of "Information asymmetry "linking the manufacturer of the drug and the consumer or patients. Who cannot make the quality assessment of their medicines.

The World Health Organization specifies that the pharmaceutical sector should have very effective and needful laws and regulations because: -

● Considerations involving the entire populace (medicinal concern)
● Manufacturers, healthcare providers, salesmen, and patients are the parties involved.
● The quality of the product cannot be determined by the consumer [3].

3. Drug Regulatory Authorities Of India [1]

The various regulatory bodies regulating the Indian pharmaceutical sector are listed below:

- CDSCO
- ICMR
- NPPA
- IPC

3.1. Central Drug Standard Control Organization

The CDSCO is the national and most important regulatory body for pharmaceutical products, Medicinal devices, and conduction of Clinical trials [4]. CDSCO works for both Central and State level organizations. The Headquarters of CDSCO is situated in New Delhi [1]. Within the CDSCO the Drug Controller General of India (DCGI) is responsible for pharmaceutical and medical devices observation and supervision.

The DCGI is advised by the Drug Consultative Committee (DCC) and the Drug Technical Advisory Board (DTAB) [5]. The CENTRAL DRUG TESTING LABORATORY (CDTL), a national statutory laboratory of the government of India for grade control of medicinal products and cosmetics, and accepted under the present D&C Act [6].

3.1.1. Functions Of CDSCO:[1]

- CDSCO plays a major role in controlling imported pharmaceutical medicinal products.
- CDSCO is authorized to approve new drugs.
- CDSCO provides permission for the conduction of effective Research studies and trials.
- CDSCO has its role in setting up the standards for cosmetics and medicinal devices.
- Assures safety, quality, and efficacy of the medicines in the market match the standards and that comply with relevant rules and regulations.
- The DCGI under CDSCO is accountable for certain classes of products like Vaccine, Sera, blood substances, and Intravenous fluids.
- The authorities at the state level are responsible for the regulation of the trade, production, and Dispersion of medicines.
- The central drug laboratories involved in the testing of the drugs.
- Role in banning drugs and cosmetics.
- Prevision of licenses, No objection certificates, Personal licenses, etc.
- Pharmacopoeia is “Pharmacon” which means drugs and “poiea” which means to make. It is a legal and standard documented book provided by the recognized authorities [1].
- Administrative structure of CDSCO is shown in Fig 1, as follows, [4]

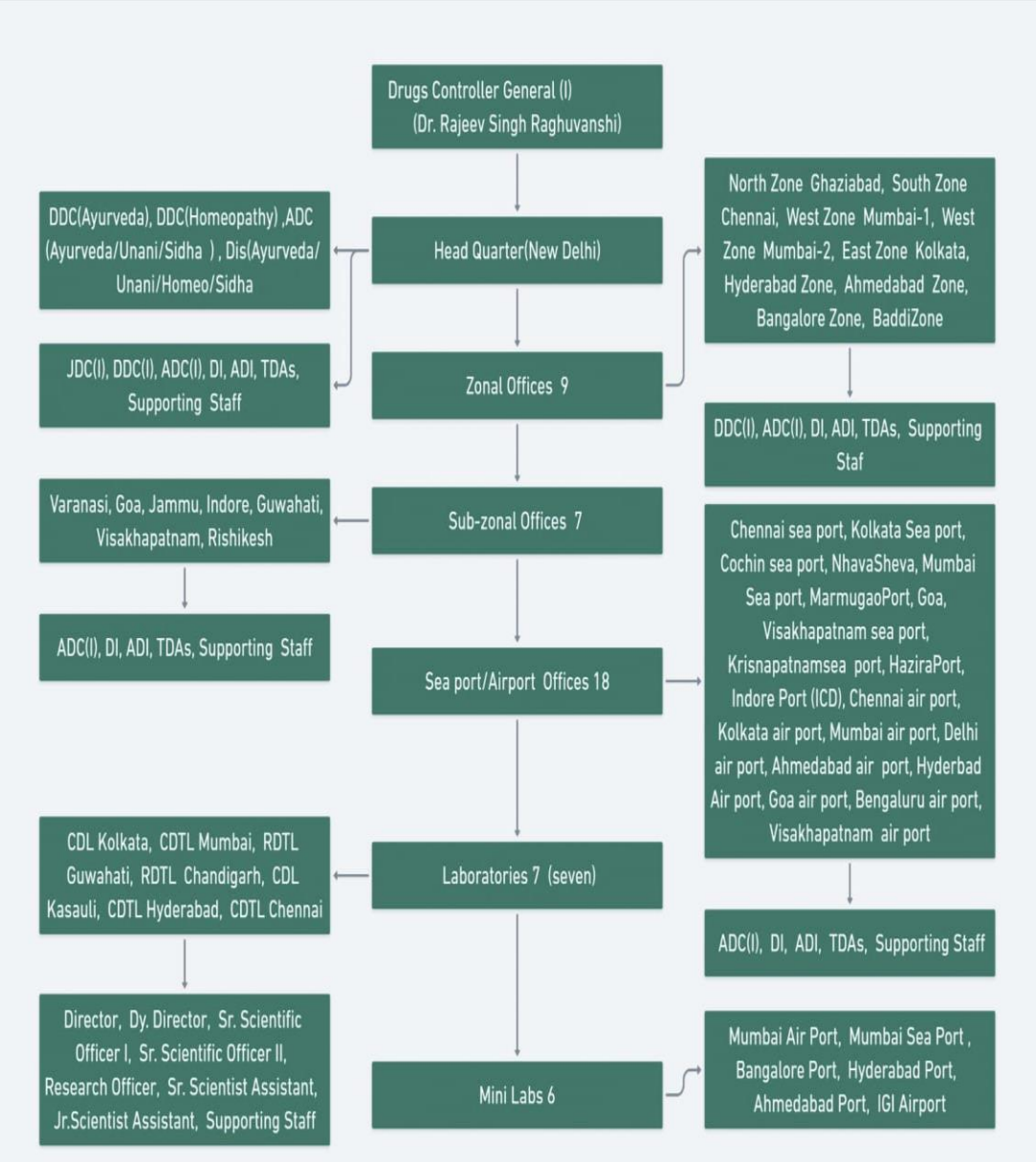

Fig 1. Flow chart of CDSCO organization

3.2. Indian Council Of Medical Research

The ICMR is known as one of the aged medical research bodies on the globe. ICMR is the top regulatory body in India for regulatory purposes. ICMR coordinates, formulates, and promotes the medicinal products. The organization is funded by the Indian government through MoHFW [1]. In 1911, the Indian Research Fund Association was built [1]. IRFA is accountable for funding and managing the medicinal study in India. According to the Declaration of Helsinki, the researches that involve human subjects should be performed by ethical principles and procedures [7].

3.2.1. Functions Of ICMR

- Major areas focused by the research are the management and control of communicable diseases.
- Controlling diseases through nutrition.

- Control of fertility, maternal health, and child health.
- ICMR focuses on non-communicable disorders like Cancer, Cardiovascular, Diabetes, Blindness, Haematological disorders, and others [1].

3.3. National Pharmaceutical Pricing Authority

The NPPA works towards ensuring the availability and accessibility of essential medicines at economical prices. It regulates and controls the prices of medicines in India under the Drugs Prices Control Order (DPCO). The NPPA regularly reviews and fixes the maximum retail prices (MRPs) of essential medicines to prevent excessive pricing and promote affordability [8]. NPPA also publishes the list of maximum selling prices of medicines. NPPA has increased the price of medicines underneath the National List of Essential Medicines (NLEM) by around 10% and the maximum selling price of medicine is based on the wholesale price index (WPI) data that is obtained from the office of the Ministry of Commerce and Industry [1].

3.3.1. Functions Of NPPA

- The availability of the medicines is functioned by NPPA.
- Sponsor-related studies concerning the pricing of medicines
- Provisions of drugs and medicine are implemented and enforced by NPPA.
- Dealing with the legal issues that occurred due to authorities.
- Maintaining solid data concerning production, exportation, and importation [1].

The administrative structure of NPPA is shown in Fig 2 as follows, [8]

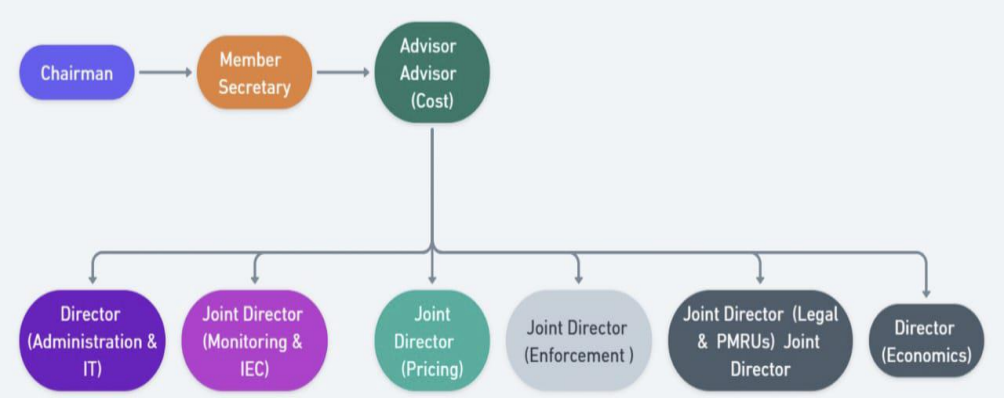

Fig 2 Organizational chart of NPPA

3.4. Indian Pharmacopeia Commission (IPC)

IPC is an independent institute established in 2005 by the Ministry of Health and Family Welfare. IPC is responsible for publishing the Indian Pharmacopeia (IP) in the country, The organization has published IP at regular intervals. The 1st official edition of IP was published in the year 1955, and the latest official 9th edition of IP was published in 2022, which is implemented from 1st December 2022[2].

IPC is accountable for the grade standards of medicines manufactured and retailed in India. The Indian Pharmacopoeia (IP), provides guidelines and standards for drug formulation, testing, and quality control. The IPC collaborates with various stakeholders, including pharmaceutical manufacturers, researchers, and regulators, to ensure the well-being and effectiveness of drugs in the market [9]. Various edition of Indian pharmacopeia published year is shown in Fig 3 as follows, [7]

3.4.1. Functions Of IPC

- IPC establishes the standards of drug
- Rationale for use of the generic medicines is encouraged (National formulary of India).
- IPC specifies the standards for identification of medicines for human and animal health care [7].

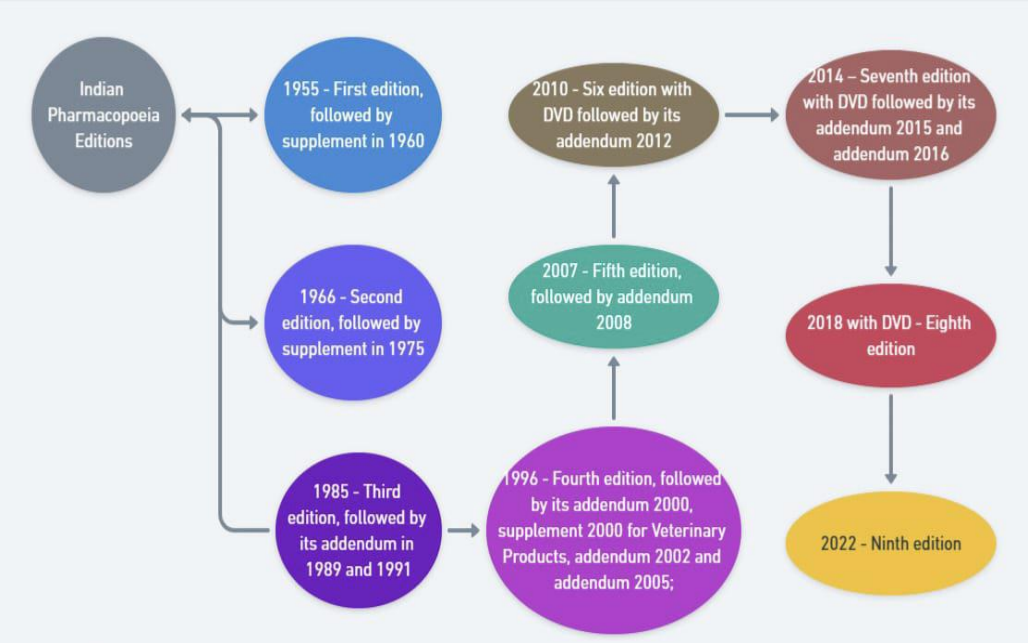

Fig. 3. History of the publication of IP edition

4. Conclusion

The Indian pharmaceutical sector is subject to strict regulation by various bodies to safeguard public health and ensure the availability of safe and effective medicines. The CDSCO, NPPA, ICMR, IPC, and SDRA collectively work together to maintain high-quality standards and regulate the industry to safeguard public health and ensure the availability of safe and effective medicines.

References

[1]Agarwal NB, Karwa M. Pharmaceutical regulations in India. “In Pharmaceutical Medicine and Translational Clinical Research” (pp. 215-231)2018. Academic Press.
[2]Jadaun GP, Rastogi S, Kumar A, Chauhan J, Sharma SK, Kumar M, Saini PK, Tiwari R, Raghuvanshi RS. “Ensuring the quality of medicines in India: An update on the development, modernization, and harmonization of drug standards in the Indian Pharmacopoeia”. Saudi Pharmaceutical Journal. 17:101825 (2023).
[3]Al-Worafi YM. “Medications registration and marketing: safety-related issues”. In Drug Safety in Developing Countries (pp. 21-28)2020. Academic Press.
[4]Central Drugs Standard Control Organization (CDSCO): www.cdsco.gov.in
[5]Mankar, Someshwar & Gholap, V & Zende, T & Dighe, R. DRUG REGULATORY AGENCIES IN INDIA, USA, EUROPE AND JAPAN-A REVIEW. “INTERNATIONAL JOURNAL OF INSTITUTIONAL PHARMACY AND LIFE SCIENCES”. 4. 2249-6807(2014).
[6]Zareen SR, Ahmed O, Reshma MS, Rasheed A. “European Journal of Biomedical”. ;10(2):113-5(2023)
[7]Seth SD, Singh S, Mohua Maulik. Indian Regulatory Framework.;89–118 (2011 Jan 1).
[8]National Pharmaceutical Pricing Authority (NPPA): www.nppaindia.nic.in
[9]Indian P (Karwa, 2018) pharmacopoeia Commission (IPC):www.ipc.gov.in