Review Article

Implementation of Drugs And Cosmetics Act, 1940 in State of Jammu & Kashmir: An Overview

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ABSTRACT

Drugs Regulation in India is governed by the Drugs and Cosmetics Act, 1940 and it has been the focus for policy reforms efforts in India, starting with Mashelakar Committee Report in 2013 to most recent report of Ranjit Roy choudhary report in 2013. Nevertheless the regulatory structure continues to be plagued with several structural challenges, including issues related to regulatory harmonisation between centre ant the states, transparency, which have been undermined the general effectiveness of the regulatory system. This study, evaluates the administrative structure and functions of drug regulatory authorities at state level. The Central Drug Control Standard Organization (CDSCO) generally concerned with policy & making of laws and rules. It deals in licensing work such as approval of licence meant for manufacture of Large Volume Parenteral, Vaccine & Sera, Blood Bank and Blood Components, Medical devices and products manufactured by Recombinant technology, concerned with new drug clearance, clinical trials, import registration, import of drugs etc., and inspections. The Jammu & Kashmir State Drugs Control Department deals with licensing of both manufacturing and sales establishments of Drugs & Cosmetics.

Keywords: Regulation, Jammu & Kashmir, Education, Health, Drug.

INTRODUCTION

Jammu and Kashmir

Figure 1: Map of J &K

Jammu and Kashmir is a state in northern India, often denoted by the acronym J&K. It is located mostly in the Himalayan mountains, and shares borders with the states of Himachal Pradesh and Punjab to the south. Jammu and Kashmir has an international border with China in the north and east, and the Line of Control separates it from the Pakistani-administered territories of Azad Kashmir and Gilgit-Baltistan in the west and northwest respectively. The state has special autonomy under Article 370 of the Constitution of India. Srinagar is the summer capital, and Jammu is the winter capital. Jammu and Kashmir consists of three divisions: Jammu, Kashmir Valley and Ladakh, and is further divided into 22 districts. Kishtwar, Ramban, Reasi, Samba, Bandipora, Ganderbal, Kulgam and Shopian are newly formed districts. Figure no.1 [1]

Introduction

Drug is the greatest weapon available to mankind to fight Disease and Death. Hence, Drug is the only commodity which cannot be compromised for any reason. Hence the need for an efficient Drugs Control Administration, to supervise the quality, availability at affordable price of drugs plays a pivotal role. The Government of India enacted the "Drugs Act" in 1940 to regulate the import, manufacture, distribution and sale of drugs and received the ascent of the Governor General on 10th April 1940. The Drugs Rules were framed during 1945 to give effect to the provisions of the Act. In the year 1962, Cosmetics were brought under the purview of enforcement and then onwards the Act has been titled as "The Drugs and Cosmetics Act". India being a federal country, regulatory competence for drug regulation is shared between the centre and the states. The study of administrative structure and functioning of drug regulatory authorities at centre and states levels in India focusing on functioning of central drugs standard control Organization (CDSCO), the national level regulators, and State drugs Regulatory Authorities (SDRAs) in India which are governed by the Drugs and Cosmetics Act, 1940. Examining the amount and the scale of the regulatory challenges facing the administrative structures and functioning of state drug regulatory authorities in India. Drugs & Cosmetics Act, 1940 and Rules 1945 recognizes mainly three Functionaries to implement the provisions of the Act and Rules-

Inspector

The State Government by notification in the Official Gazette appointed Drugs Inspectors to be Inspectors under Section 21 of Drugs and Cosmetics Act, 1940 for areas assigned to them.

Licensing Authority

Drugs Controller is Licensing Authority for manufacturing / sales Establishments. However, with the approval of state government, the power to issue licenses to Sales Establishment has been delegated to all Assistant Drugs Controllers located at Circle offices.

Controlling Authority

Drugs Controller has the mandate to function as controlling authority and all inspectors are officially discharging their duties as sub-ordinate officers. [2]

Research and Methodology

- The primary research study includes challenges confronting the current drug regulatory system. The findings and analysis of the study are based on legal and policy analysis, stakeholder interviews and information gathered through RTI applications and Department websites. Although the Drugs and Cosmetics Act, 1940(hereafter referred as DCA) is a central legislation, given that health is a state subject matter, the state exercise enormous control over the manner in which it is implemented in the state, from financial allocation to SDRAs to interpretation of specific provisions of DCA. The main purpose of this study is to evaluate different kinds of regulatory frame works in existing in India and to explain why one works and another fails.. In this Jammu and Kashmiri state one of the most important state of India was selected based on their Functional activities, Duties and administrative structure at enforcement and Drugs testing Laboratory.

Food and Drugs Control Organisation Jammu and Kashmir

A full-fledged Organization of Drug and Food Control came into existence after its bifurcation from Directorate of Health Services J&K, with an objective of ensuring availability of standard, safe & quality drug and food articles to the public.

History of Department

The Drug Control Wing was established in the State in the year 1964 under the administrative control of Directorate of Health Services, J&K and remained so till the year 1987. In the year 1987, Drugs and Food Control Organization was a part of Directorate of Health Services until 1987 when a full flagged organization came into existence, primarily to check the quality of Drug and Food Articles. The concept of FDA has been presumably conceived from similar arrangement that existed in some other progressive States of the country.

The Drugs & Food Control Organization J&K is the Nodal Agency for the implementation of following regulations in the State. Figure no.2

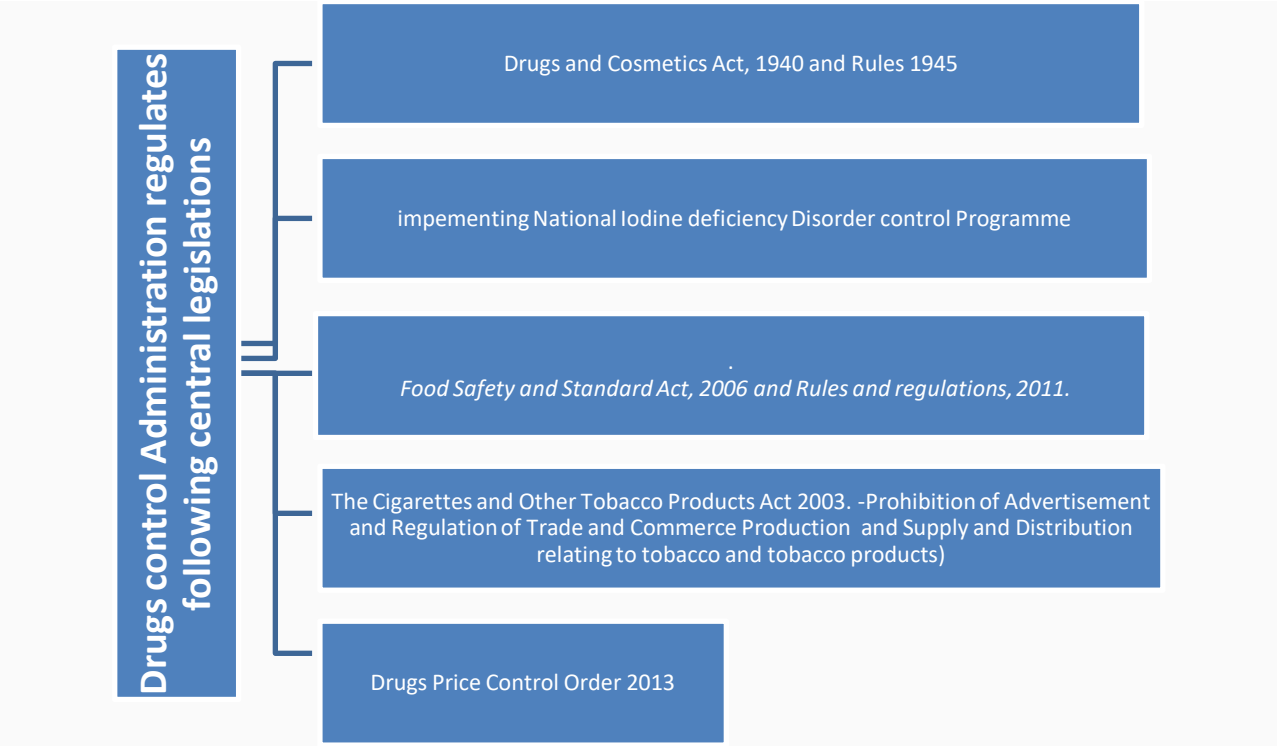

Figure 2: Regulation of Acts in the State

Functions and Responsibilities of Various officers under Drugs Control Department

State Drugs Controller

The State Drugs Controller shall be the overall in-charge of the organization. All the Drugs Control Officers who shall act as Inspectors appointed by the government shall be under his control for the purpose of administration and disposal of the work under the Drugs and Cosmetics Act 1940. The Drugs Controller shall have below mentioned functions and responsibilities

- Outlining the policies and guidelines.
- Grant of Narcotics licences in medicine formulations.
- Coordinating and arranging the meetings of the department.
- Grant of prosecution orders in contravention of legal provisions.
- Periodical review of the performance of Drugs Control Officials subordinate to him.
- • Initiation of the annual confidential reports of Drugs Control Officers and Zonal Assistant Drugs Controllers.
- Approval of Drugs Formulations of highly sensitive products such as vaccines, Seras, Large Volume Parenterals and Cyto-toxic products. Grant of Certificate of Pharmaceuticals products (COPP) under W.H.O GMP certification scheme.
- Attending the meeting of national/ international levels.
- Regulation of sale and distribution of highly sensitive products.
- State Administrative Head of the Department
- Licensing Authority of Drug Manufacturing Establishments (including Ayurveda) with mandatory statutory qualification as laid down in the Drugs & Cosmetics Act, 1940
- State Food Health Authority
- Member Secretary state level Apex Committee constituted for implementation of Cigarettes & Other Tobacco Products,(Prohibition of Advertisement & Regulation of Trade and Commerce, production, Supply and Distribution) Act,2003.
- Ex-offico President J&K Pharmacy council.

Deputy Drugs Controllers

The Deputy Drugs Controller will be incharge of their respective zonal offices at the aforementioned five locations and shall have below mentioned functions and responsibilities:-

- Grant and renewal of retail sale drugs licences.
- Ensure to cause at least one inspection in a year of all the establishments/ licensed for the sale of drugs within the area of his zone.
- Monitoring of investigation reports pertaining to spurious/ not of standard quality drugs and their timely actions.
- Monitoring of institution of prosecutions in respect of breaches of the Act and Rules made there under.
- Guidance to the Drugs Inspectors in technical matters and in prosecution cases.
- Actions against the chemists for suspension or cancellation of retail sale drugs licences under the provisions of Rule 66.
- Filing of replies against the appeals in matters of suspension/ cancellation of retail sale licences.
- Filing of replies in various cases of suspension/ cancellation of retailers and in other matters.
- Collection of data/ information for replying to Parliament/ Rajya Sabha/ Assembly questions or supplying information to the CDSCO.
- Arranging awareness programs for the public and for the chemists etc.
- Inspect the drugs manufacturing units and blood banks with assistance of Drugs Inspectors.
- Monitoring and supervising of inspections of sales establishments.
- Disposal of applications under R.T.I Act 2005.
- Monitoring the quota of drugs sample allocated to each inspector in his zone.
- To get investigated the complaints against the chemists/ manufacturers successfully at an early date.
- Divisional Administrative Heads;
- Licensing Authorities possessing statutory qualifications under the Act for licensing of whole sale establishments under the Drugs & Cosmetics Act, 1940 and Rules there under.
- Local Food Health Authority
- Liaison officers to monitor activities under Cigarettes & Other Tobacco Products,(Prohibition of Advertisement & Regulation of Trade and Commerce, production, Supply and Distribution) Act,2003

Assistant Drugs Controller

The Assistant Controller Drugs have been appointed as Licensing Authority and shall have functions and responsibilities as under:-

- To assist the State Drugs Controller and Joint Drugs Controller.

- Shall file the replies against the writ petitions filed against the department.
- Organize the trainings for the Assistant Drugs Controllers and Drugs Inspectors.
- Grant and renewal of whole sale drugs licenses.
- Random verification of recommendation of whole sale licences by the Drugs Inspectors.
- Implementation of Drugs Price Control Order 1995, Indian Medical Council Act 1956, Implementation of Cigarette and other tobacco products Act 2003 etc.
- Regulation of sale of alleged to be habit forming drugs.
- Collection of information regarding manufacture, sale and distribution of spurious, Not of Standard quality drugs, habit forming drugs through watchers/ informers and ensuring the actions against the culprits.
- Scrutiny of the applications for grant of whole sale licences.
- Ensure the expedition of prosecution orders against the persons/ firms without license and in respect of spurious/ not of standard quality drugs within a period of 6 months or before the expiry of the drugs whichever is earlier.
- Arranging meetings for deciding the cases pertaining to spurious drugs as per guidelines of Central Drugs Standards Control Organization.
- Disposal of complaints against the chemists and unregistered medical practitioners.
- Arranging joint raids to check the menace of habit forming drugs.
- Collection of data and filing replies in matters of Parliament/ Rajya Sabha/ Assembly Questions or supply of information to Central Drugs Standards Control Organization.
- The ACDs have been entrusted with additional assignment of enforcement of the: Cigarettes & Other Tobacco Products,(Prohibition of Advertisement & Regulation of Trade and Commerce, production, Supply and Distribution) Act,2003

Duties and Responsibilities of Drugs Inspectors

- Inspect pre licensing establishment.
- Inspect post licensing establishment not less than once in a year to satisfy himself that the conditions of the licences are being observed and are intact.
- Procure and send samples for test and analysis.
- Detect the contraventions if any.
- Investigate any complaints against the retailer/ whole seller and manufacturers etc.
- Investigate the matter w.r.t. spurious/ adulterated/ not of standard quality drugs make enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act/ Rules.
- Maintain records of all inspections made and action taken by him in the performance of his duties and submitting the information to the controlling authority to detect the import of drugs into the state which is prohibited.
- Institution of prosecutions in respect of the breaches of the Act and Rules there under.
- Inspect not less than once a year the manufacturing premises if specially authorized.
- Filing of replies in court cases.
- Defending the cases launched in the court of law.
- Disposal of applications under R.T.I. Act.
- Implementation of provisions of the Drugs and Cosmetics Act 1940 and Rules 1945, Drugs Price Control Order 1995.

v) Drug Analyst

The Drug Analyst shall be the overall incharge of the Drug Testing Laboratory, shall have administrative control on the other subordinate officers and shall have the below mentioned functions and responsibilities:-

- Shall act as Notified Government Analyst.
- Shall be in charge of secrecy for receiving and distributing the samples to the scientific and junior scientific officers.
- Shall guide the Senior Scientific and Junior Scientific Officers.
- Shall be responsible for accreditation of the laboratory from NABL.
- Shall review the performance of the officials subordinate to him.
- Shall be responsible for purchase of the chemicals and reagents on day to day basis.
- Monitoring of the equipment and their periodical maintenance.
- Shall be responsible for validation and revalidation of the methods/ techniques.
- Shall be responsible for arranging the periodical audit of the lab and for corrective action & preventive action (CAPA).
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The Senior Scientific Officers and Scientific Officers
The Senior Scientific Officers and Scientific Officers shall have the below mentioned functions and responsibilities:

- They shall be notified as analyst for the purpose of test and analysis of the drug samples including samples of schedule C drugs.
- Shall device the SOPs for each and every activity.
- Shall calibrate all the lab equipment and instruments.
- Shall declare the status of equipment/ instruments.
- Shall validate/ revalidate the standardization of chemicals or reagents
- Shall store the raw data/ worked out data.
- Shall be responsible of archival and retrieval of the test and analysis data of the drugs.

Lab Attendants

The Lab Attendants shall have the functions and responsibilities as under:-

- Monitoring cleaning and sanitation in the lab.
- Collection and transfer of material required for the lab use.
- Cleaning and drying of the Apparatus.
- Monitoring cleaning and maintenance of lab instruments and equipment.
- Operation of autoclave etc.
- To assist the Senior Scientific, Scientific and Junior Scientific Officers in their day to day work.
- Dispatch of test reports.
- Disposal of left- over quantity of the used sample portions.3

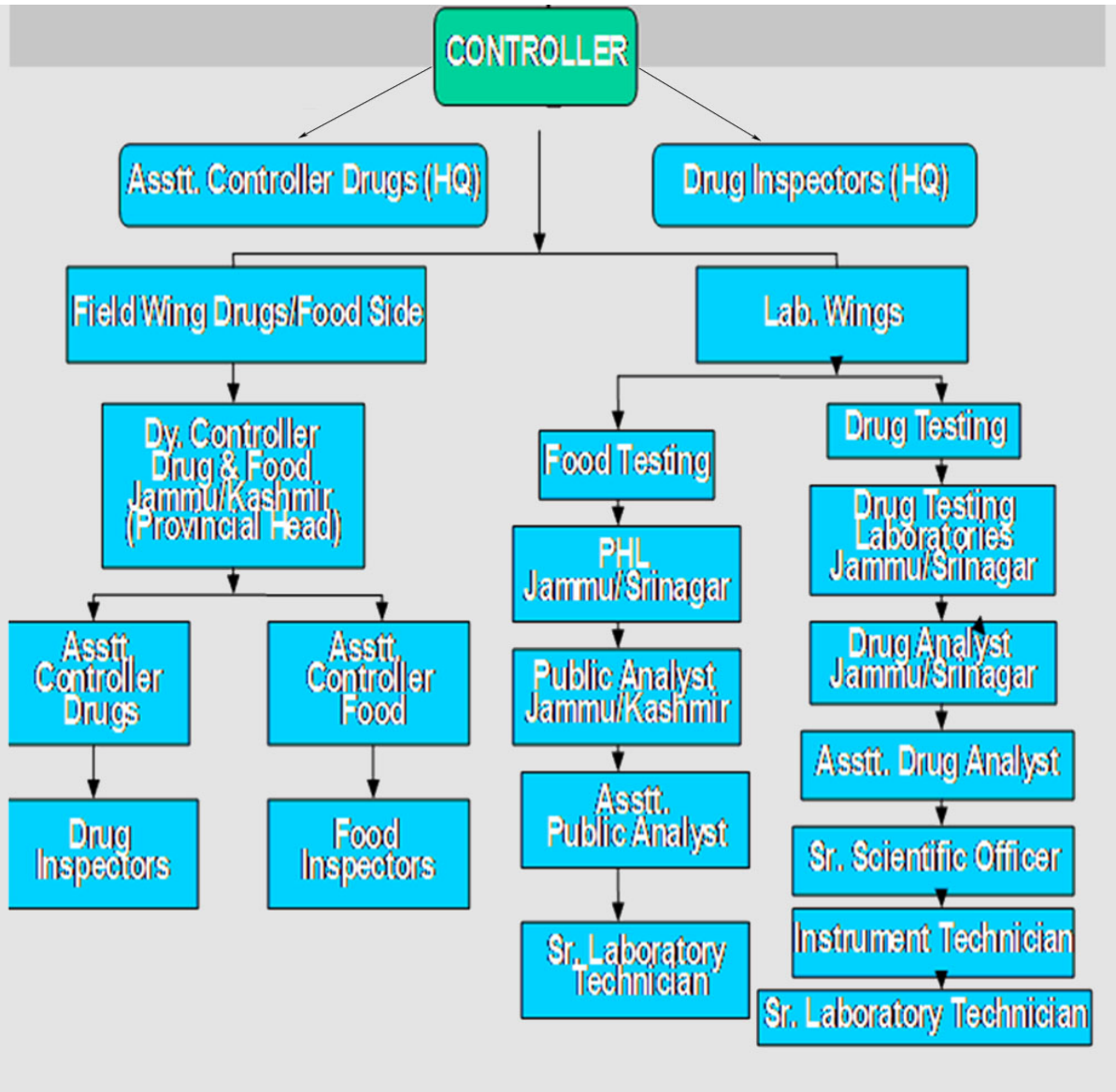

Figure 3: Organogram of Food and Drugs Control Organization

Drugs Testing Laboratory

There are two labs existing one at Jammu and One in Kashmir. The Each Labs are headed by Drug Analyst are notified as Government Analyst for the purpose of Drugs and Cosmetics Act 1940, Rules there under. The state has also notified Karnataka Senior Scientific Officers as Government Analyst. (Figure no.3)

Pharmaceutical Industry

- Jammu and Kashmir with presence of companies like Sun Pharma, Cadila, and Piramal Healthcare, Jammu and Kashmir has emerged as the major pharmaceuticals manufacturing destination in the country. Cadila Pharmaceuticals Ltd is an integrated healthcare solutions provider catering to over 45 therapeutic areas. The company has a manufacturing facility at samba in Jammu. More than 100 pharmaceutical units operating in industrial areas of Jammu and Kashmir.
- I/ Ayurvedic/Siddha/Unani/Homeopathic Drug Manufacturing Units 24 units
- II Allopathic Drug Manufacturing Units in J&K (including Cosmetics) 88 including 9 Cosmetics Loan Licensee -21 and Blood Banks 48 and 2 component 1 apheresis. Figure no.4
- There are about 17500 Retailer and 7000 wholesalers in the state.4,5

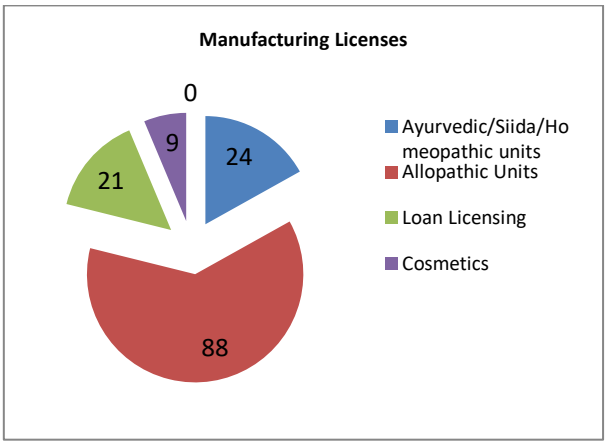

Figure 4: Manufacturing Licenses in the state

RESULTS AND DISCUSSION

Regulatory responsibilities are divided into central drugs standard control Organization (CDSCO), the national level regulators, and State drugs Regulatory Authorities (SDRAs) The division may create the risk of fragmentation. Both are entitled to implement the DCA autonomously. Lack of uniformity in legal interpretations of DCA, and regulatory decision in making central and state a challenge. There is no interaction and coordination between central and states. (Granting of fixed dose combination by state Licensing Authorities). In some of the Regulated countries (China) the all the applications are first approved by the local authorities then Central Drug Authority is the final authority for approval. There is no flexibility in decision making finance, recruitment and policy making. There is lacuna in pay, work conditions facilities and training. The physical structure of state laboratories vary in terms of quality and capacity there is a need to provide good infrastructure Laboratories, E- licensing digital database with good investment and expansion facilities at state Level..

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CONCLUSION

The State Drugs Control Department deals with licensing of both manufacturing and sales establishments of Drugs & Cosmetics. Undertaking the inspections of such premises to ensure compliance with license conditions, drawing samples for testing and monitoring of quality of drugs, taking actions like suspension/cancellation of Licenses, surveillance over sale of spurious drugs and adulterated drugs, instituting legal prosecution when required and monitoring objectionable advertisements for drugs. The major challenges confronting the Indian Drug regulatory system is that, there is no single entity which is ultimately responsible for ensuring the regulatory effectiveness of the system as a whole. Jammu and Kashmir State Drugs Control Department tied to their parent ministries and department of health respectively. This requires flexibility in decision making and autonomy in a host of areas including financial autonomy, recruitment and others areas on institutional policy. Hence requires the harmonization of implementation of Drugs and Cosmetics Act 1940 and Rules 1945 among the States of India.

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