

# Implementation of Drugs & Cosmetics Act 1940 and Rules there under in Odisha: A Overview

<sup>1</sup>Kempaiah Suresh, <sup>2</sup>Balamuralidhara V., <sup>3</sup>S.B.Puranik

<sup>1</sup>Research Scholar, <sup>2</sup>Assistant Professor, <sup>3</sup>Head Regulatory Affairs

<sup>1,2</sup>Regulatory Affairs Group, Department of Pharmaceutics

<sup>3</sup>Anthem Biosciences

**Abstract:** Odishahas been one of the Eastern State of India. Drugs Regulation in India is governed by the Drugs and Cosmetics Act, 1940 and it has been the focus of several recent policy reforms efforts in India, starting with Mashelkar 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 and 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 Parenterals, 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 Odisha State Drugs Control Department deals with licensing of both manufacturing and sales establishments of Drugs & Cosmetics.

**Keywords:** Regulation, Odisha, Education, Health, Drug.

ODISHA

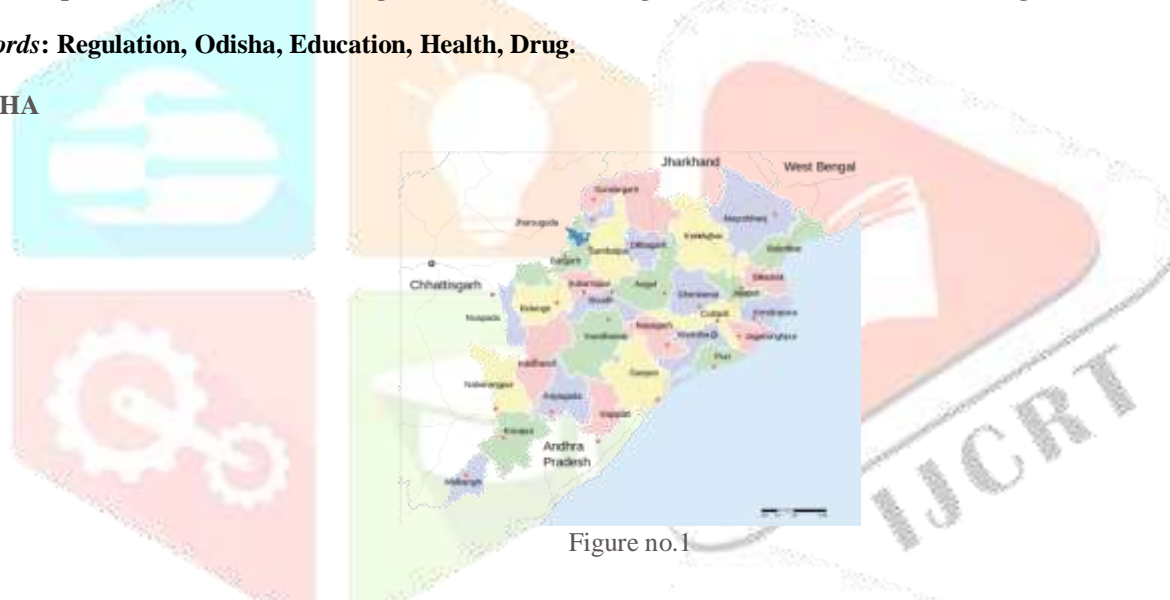


Figure no.1

- Odisha is one of the 30 states of India, located in eastern India. It is surrounded by the states of West Bengal to the north-east, Jharkhand to the north, Chhattisgarh to the west and north-west, and Andhra Pradesh to the south. It is the 9th largest state by area, and the 11th largest by population. It is also the 3rd most populous state of India in terms of tribal population. Odia (formerly known as Oriya) is the official and most widely spoken language, spoken by 33.2 million according to the 2001 Census. The modern state of Orissa was established on 1 April 1936, as a province in British India, and consisted predominantly of Odia-speaking regions. April 1 is celebrated as Odisha Day. Bhubaneswar is the capital of Odisha. (figure no.1). (1, 2)

## Introduction

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 focussing 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 drug regulatory authorities in India. 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. 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.

➤ **Directorate of Drugs Control, Odisha**

• The Directorate of Drugs Control Administration. is functioning in the building of “state drugs testing and research laboratory” situated at Gajapati Nagar, Bhubaneswar, Orissa. Established in the year 1947 under Directorate of Health Services and became an independent Directorate since 1982. It’s administrative Wing at Bhubaneswar consisting of One Drugs Controller, two Dy. Drugs Controllers, three Asst. Drugs Controllers and two Drugs Inspectors. The Drugs Controller, Odisha is the Controlling Authority and Head of the Department. He is also the Chairman for Board of Examinations for Diploma in Pharmacy. He is also the Licensing Authority of the State for licenses to manufacture for sale of Allopathic drugs, Homoeopathic drugs and Cosmetics and Licensing Authority for sale licences of 17 nos. of ranges other than those coming under Western Zone & South Zone. There are two zonal offices namely Dy. Drugs Controller (South Zone) situated at Berhampur and Dy. Drugs Controller (West Zone) situated at Sambalpur. The Dy. Drugs Controller (South Zone), Berhampur is the Licensing Authority for sale licences for 12 nos. of Range offices and Dy. Drugs Controller (West Zone), Sambalpur is the Licensing Authority for sale licences for 11 nos. of Range offices and Dy. Drugs Controller (Administration) is delegated with power to sign licences pertaining to sale licences of Homoeopathic and Allopathic drugs for remaining 17 nos. of Range offices. There are 40(Forty) range offices of Drugs Inspectors in the State under the administrative control of the Drugs Controller.

a. This organization is functioning mainly with two wings (i) Administrative wing, (ii) Testing wing.

b. The administrative wing functions with: - **One** Drugs Controller, **4** Dy. Drugs Controller, **4** Asst. Drugs Controllers & **44** Drugs Inspectors and have two zonal offices at Berhampur and Sambalpur with **40** range offices.

c. The Testing wing (i.e. State Drug Testing & Research Laboratory, Odisha, Bhubaneswar) functions with:- **One** Principal Scientific Officer, **3** Senior Scientific Officer, **12** Junior Scientific Officer & **27** Senior Laboratory Assistants(3,4)

1.	Functions	undertaken	by	State	Government
2.	Licensing of drug manufacturing and sales establishments.				
3.	Licensing of Drug Testing Laboratories.				
4.	Approval of Drug Formulations for Manufacture.				
5.	Monitoring of quality of Drugs & Cosmetics, manufactured by State Units and those marketed in the State.				
6.	Investigation and prosecution in respect of contravention of legal provisions.				
7.	Administrative Actions.				
8.	Pre and Post-Licensing Inspections.				
9.	Recall of Not of Standard Quality/ Spurious/ Misbranded/ Adulterated/ Prohibited Drugs.				
10.	Sampling of Drugs & Cosmetics for Test or Analysis to ascertain their quality.				
11.	Verification of labels of Drugs & Cosmetics.				
12.	Verification of utilisation of Narcotic drugs in licensed premises.				
13.	Verification of prices of both scheduled and non-scheduled formulations under D.P.C.O.-2013.				
14.	Grant / Renewal of Blood Bank licences to Govt. institutions as well as to Private Hospitals.				
15.	Approval of Blood Storage Centres.				
16.	Grant of N.D.P.S.-1 & N.D.P.S-2 Licences for manufactured and sale of Narcotic drug formulations (Allopathic & Ayurvedic containing Narcotic drugs (3,4)				

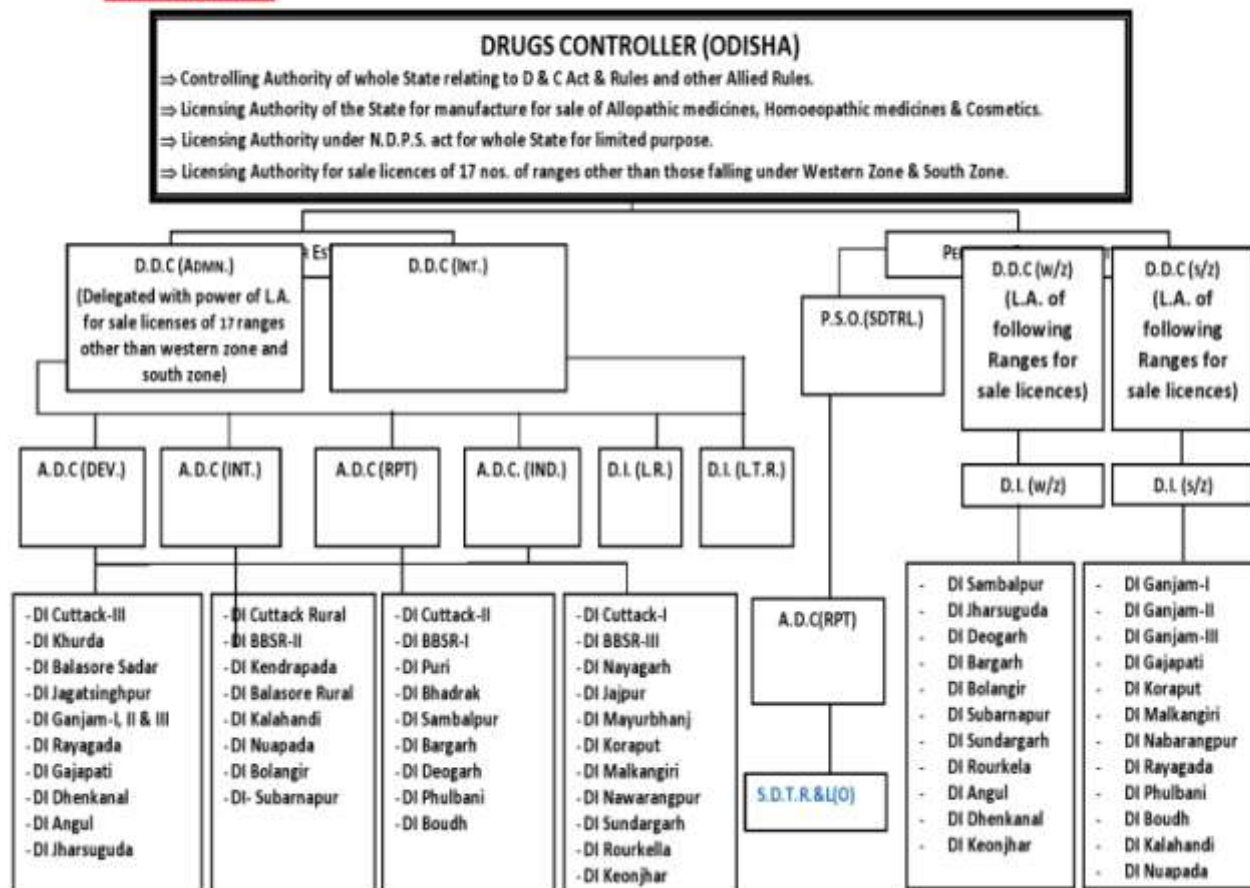
**ORGANOGRAM:**

Figure no.2 Administrative structure of Drugs Control Administration Odisha

## ➤ Implementation of the following Acts, Rules and Orders in state of Odisha

1. To enforce Drug & Cosmetics Act 1940 and Rules 1945 (to provide quality medicines).
2. To enforce Drugs (Price Control) Order 2013 read with the Essential Commodities Act, 1955 (to make drugs available to public as per price fixed by the National Pharmaceutical Pricing Authority, New-Delhi (N.P.P.A) under ministry of Chemicals and Fertilisers, Department of Pharmaceuticals).
3. To enforce D.M.R.O.A. Act 1954 & Rules 1955 (to check false claimed and advertisement pertaining to drugs and diseases).
4. To issue N.D.P.S. Licences under N.D.P.S. Rule 1989 for limited purpose. (Grant of Licences in Form-NDPS-1 & NDPS-2 and issued of transport permit for manufactured drugs to transport them intra and inter state).
5. The Cigarettes and Other Tobacco Products Act, 2003.

## ➤ Function of Drugs Control Administration

1. To grant/renew the sale of drug license and also keep a close watch over the enforcement made by the district drug inspectors, within the State of Odisha.
2. To check/arrest movement of fake/sub standard medicines sale as well as manufacture.
3. To grant / renew manufacturing drug licences (Allopathic & Homeopathic)
4. To grant/ renew Cosmetics manufacturing licences.
5. To inspect manufacture premises (Allopathic / Homeopathic/ Cosmetics) as well as sales premises (Allopathic/ Homeopathic) and to draw statutory sample of drugs for Test and Analysis at statutory Laboratory to identify & stop movement of adulterated / misbranded / spurious & substandard drugs.

6. To take up verification of label of drugs towards objectionable claim, if any made by the manufacturer to prevent self medication and also misleading claims.
7. To regulate sale of manufactured narcotic drugs under N.D.P.S. Rules 1989 through proper prescription to prevent drug abuse.
8. To ensure that the drugs are sold at reasonable price by enforcing D.P.C.O., 2013 read with D.P.C.O., 1995.

➤ **Services**

1. Information of licensed Blood Banks.
2. Information on Blood Storage Centres.
3. Information on banned drugs.
4. Information on prices of notified drugs.
5. Information on licensed shops for allopathic and homeopathic medicines.
6. Information on licensed manufacturing units.
7. Investigation of complaints on services of chemists and druggists.
8. Investigation of complaints on adverse drug reaction.
9. Issuance of G.M.P., WHO GMP, COPP certificates to licensed manufacturers.
10. Issuance of Non-Conviction Certificates, Market Standing Certificates to licensed manufacturers.

➤ **Drugs Testing Laboratory Odisha**

The Testing wing State Drug Testing & Research Laboratory, Odisha, located at Bhubaneswar which is headed by One Principal Scientific Officer, 4 Senior Scientific Officer, 12 Junior Scientific Officer and 27 Senior Laboratory Assistants. There are four Government Analyst notified by the government of Odisha. They analyse around 4000 samples in a Year. They have one microbiology Lab, 3 Chemistry Labs and 1 Instrument Lab. There is proposal of setting up two laboratory at Bharampur and Sambalpur.(5)

- There are about 70 odd Manufacturing units in Odisha which includes cosmetics, Surgical Dressing, Medical Oxygen and 80 Blood Banks and 74 Blood Storage Centres. (Figure no.3)

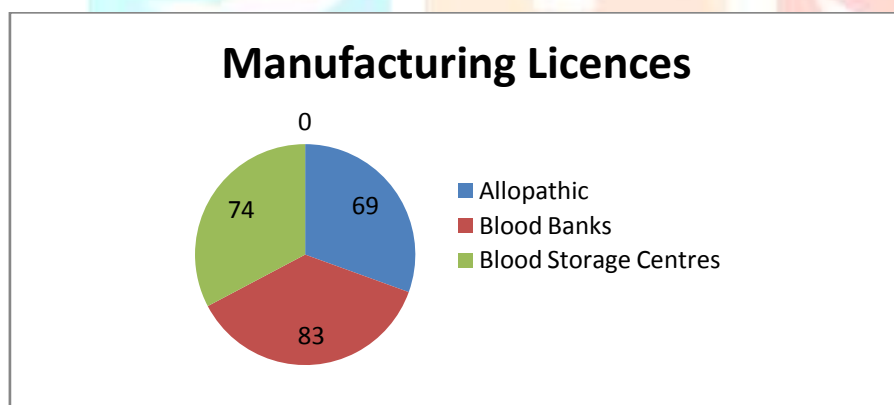


Figure no.3 Total number of Licenses in Odisha

- There are about 15000 Retailers and 6000 Wholesales in the State of Odisha (Figure no.4) (6)

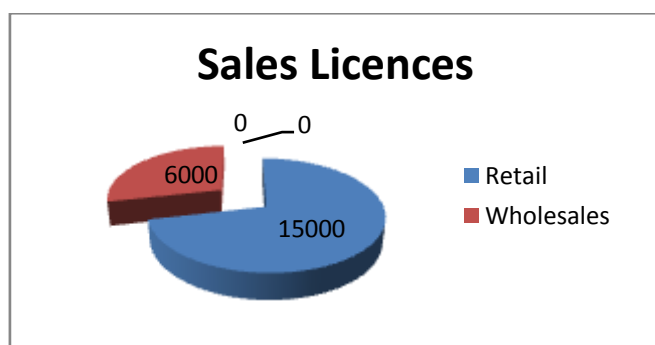


Figure no.4 Total Number of Sales Licences in Odisha

### ➤ **Odisha State pharmacy council**

Odisha State pharmacy council is located at Directorate of Drugs Control, Odisha, Bhubaneswar is functioning in the first floor of the building located near Press Chhak between Sainik School and Nalco Square. The council was formed in 20/01/1958. There are about 30916 Registered Pharmacist in the state of Odisha. There are about 65 institution catering pharmacy education in the state of Odisha.

### ➤ **Acknowledgement**

• I would like to thank Sri Sunil Kumar Nayak Assistant Drugs Controller and SmtSunitha Nag Drugs Inspector Directorate of Drugs Control for providing the learning's that made this manuscript in the best mode form.

### ➤ **Conflicts Of Interest**

The Author declares that there are no conflicts of interest.

### ➤ **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 licence 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. 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. The entire spectrum of the pharmacy related activities in Odisha are brought under one roof.

### **References**

- [1] Odisha – Wikipedia.[Internet]. [updated 23 July 17: cited 2017 December2]. Available from: org/wiki/Odishaa
- [2] [PDF] Odisha state profile The State of Odisha is located on...-[Internet]. [updated 23 July 17: cited 2017 December 2]. Available from: Ficci ficci.in/state/1009/project\_docs/state-profile-odisha.pd
- [3] OdishaGovernment[Internet]. [updated 23 July 17: cited 2017 December4]. Available from: portal odisha.gov.in/
- [4] Drug Control Administration | Department of Health & Family Welfare...health[Internet]. [updated 23 July 17: cited 2017 December 4]. Available from: .odisha.gov.in/DCA\_Who.aspGL=7
- [5] Drug Control Administration [Internet]. [updated 23 July 17: cited 2017 December7]. Available from: www.dcaodisha.nic.in/
- [6] Drugs Control Administration[Internet]. [updated 23 July 17: cited 2017 December 7]. Available from: dcodishaonline.nic.in