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Implementation Drugs and Cosmetics Act, 1940 and Rules, 1945 Among the Southern States of India

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ABSTRACT

Health is a Fundamental Right granted by the Constitution of India. The Government of India passed the “Drugs Act” in 1940 to regulate the import, manufacture, distribution and sale of drugs. The Drugs Control Administration aims at assuring the availability of drugs & Cosmetics of proven quality, efficacy and safety at prices as announced. Pharmacy is the health profession that links the health science with chemical science and it is charged with ensuring the safe and effective use of pharmaceutical drugs. In this study to identify the areas of variation in Interpretation of Drugs and Cosmetics Act, 1940 and Rules thereunder among southern states of India. These findings suggested that lot of banned fixed dose combinations are approved by the different states and difficult to track and trace the substandard drugs and different states adopting different procedure in issuing license for manufacture of drugs among states of India, and even there is a variation in Administrative Actions and implementation of the said Act also. It affects the public health. Hence it requires the harmonization of implementation of Drugs and Cosmetics Act 1940 and Rules 1945 among the States of India.

Key Words: Drugs and Cosmetics Act, Fixed dose combinations, Harmonization, Substandard drugs.

INTRODUCTION

The Government of India passed the “Drugs Act” in 1940 to regulate the import, manufacture, distribution and sale of drugs. The Drugs Act 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. Cosmetics were not included under this statute. Reports started appearing in the press that due to the absence of control measures, unscrupulous manufacturers were making attractive cosmetics like lipsticks with harmful textile colors, creams and powders etc. using toxic raw materials. Hospitals started reporting cases of obstinate skin disorders due to use of these harmful cosmetics. Hence 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**” [1,2]. The implementation of Drugs and Cosmetics Act, 1940 exist at two tiers i.e., at the

Central and State Government level:

The central drug control standard organization (CDSCO)

It is generally concerned with policy & making of laws and rules and management of committee such as Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC). It deals in licensing work such as approval of license meant for manufacture of Large Volume Parenteral, Vaccine & Sera, Blood Bank and Blood Components, Medical devices and products manufactured by Recombinant technology. It also deals with new drug clearance, clinical trials, import registration, import of drugs etc., and inspections [3-6].

The state drug control department

On the other hand, it deals with licensing of both manufacturing and sales premises of drugs & cosmetics. Its most important mandate is to ensure the supply of quality drugs at the price fixed by GOI (NPPA) to the people of the State [7-10].

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 powers to issue licenses to Sales Establishment have 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.

Objective

To identify the areas of variation in Interpretation of Drugs and Cosmetics Act, 1940 and Rules thereunder among the southern states of India

Harmonization of the interpretation of the Drugs and Cosmetics Act, 1940 and Rules thereunder among states of India (Figure 1 and Table 1).

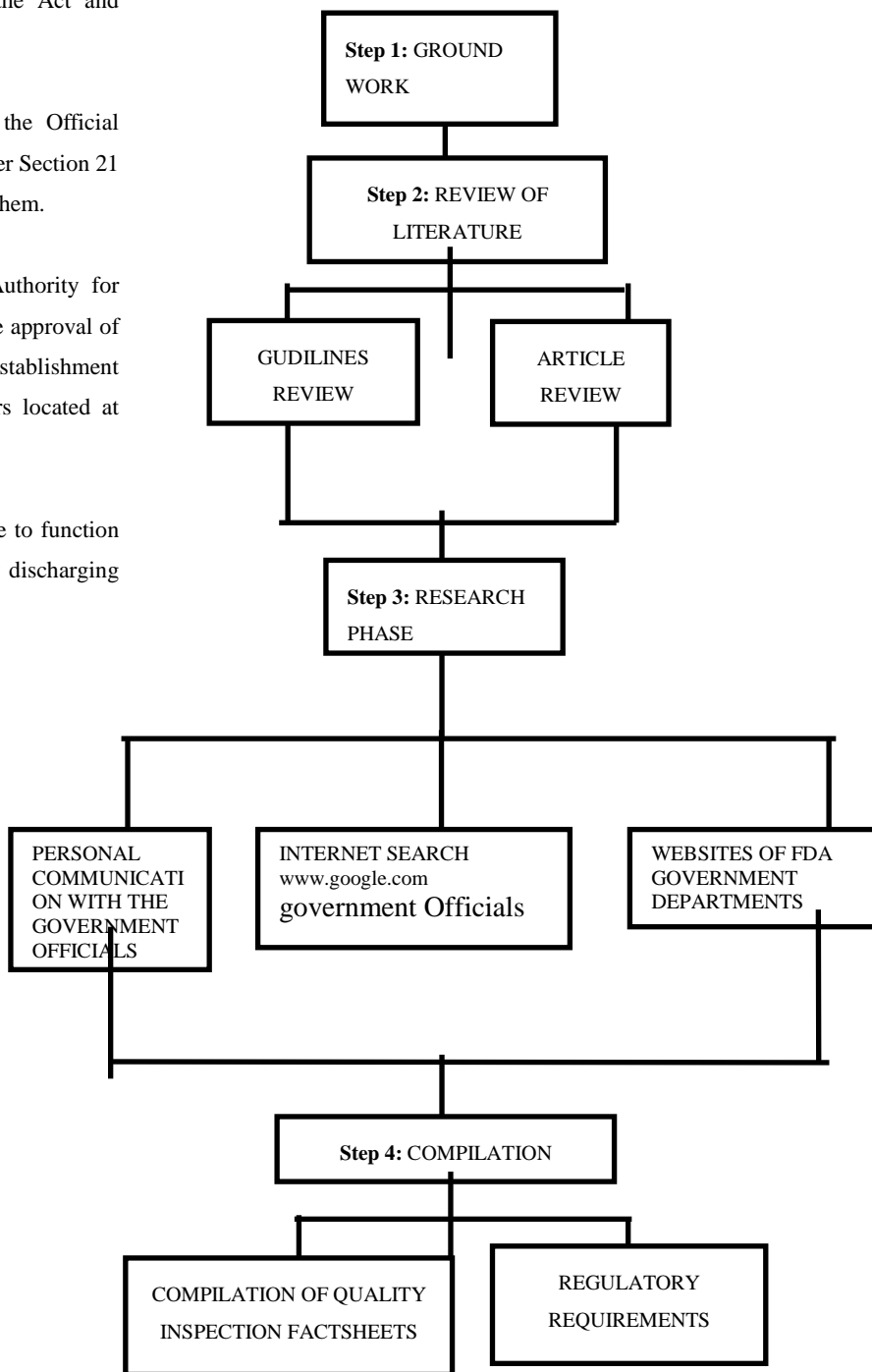


Figure 1: Flow chart showing the research methodology.

Table 1: Harmonization of the interpretation of the Drugs and Cosmetics Act, 1940 and rules there under among states of India.

	State	Karnataka	Telangana	Kerala	Tami Nadu	Andhra Pradesh	Puducherry
1	Name of the Regulatory Authority	Drugs Control Department	Drugs Control Administration	Food and Drugs Administration	Food Safety and Drugs Administration	Drugs Control Administration	Food Safety and Drugs Administration
2	Independent stand –alone Authority	Yes	No	Yes	No	No	No
3	Testing Labs	3	1	1	1	1	1
4	Licensing of Ayurvedic and Homeopathic Drugs	No	No	Yes	yes	No	No
5	Controlling Authority	Drugs Controller	Director	Drugs Controller	Commissioner	Director General	Drugs Controller
6	Licensing Authority for Sales	Assistant Drugs Controller	Assistant Commissioner	Assistant Director	Assistant Director	Assistant Drugs Controller	Assistant Drugs Controller
7	Labs Head	Principle Scientific Officer	Joint Director	Chief Government Analyst	Government Analyst	Joint director	Assistant Drugs Controller
8	Inspecting Authority	Drugs Inspector	Senior Scientific Officer	Drugs Inspector	Drugs Inspector	Joint Director	Senior Public Analyst
9	Manufacturing Licences	268	198	1300 (Including Ayurvedic)	487	468	100
10	Education	Administrative Control of Government College and Regulation of D. Pharmacy	No	No	No	No	No
11	Conducting Investigation in Substandard Drugs	No standard operating procedures	No standard operating procedures	Kerala	No standard operating procedures	No standard operating procedures	No standard Operating procedures
12	Administrative action (manufacturing)	Suspension of Licenses for different	Suspension of Licenses for different	Suspension of Licenses for different for	Suspension of Licenses for different	Suspension of Licenses for different for	Suspension of Licenses for different

	establishments)	duration no uniformity	duration no uniformity	duration no uniformity	duration no uniformity	duration no uniformity	duration
13	Administrative action (Sales establishments)	Suspension of Licenses for different duration no uniformity	Suspension of Licenses for different duration no uniformity	Suspension of Licenses for different duration no uniformity	Suspension of Licenses for different duration no uniformity	Suspension of Licenses for different duration no uniformity	Suspension of Licenses for different duration

RESULTS AND DISCUSSION

Both Central and State authority are entitled to implement the Drugs and Cosmetics Act, 1940 and Rules thereunder autonomously. There is no interaction and coordination between central and states. (Granting of fixed dose combination by state Licensing Authorities). 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. There is lack of uniformity in administrative actions taken by different state authorities as a result of which each state suspends manufacturing licenses for different durations. The lack of uniform nationwide standard operating procedure for drug inspectors conducting investigations into sub-standard drugs thereby leading to a significant difference in the manner in which cases are prosecuted in different parts of the country. Sentencing guidelines for judicial courts. Filing of the Cases in the courts. Agenda to discuss various procedures and Standard Operating Procedures for uniform implementation of Good Manufacturing Practices and other inspections, with intent to bring speed and transparency and to ensure patient safety. Fixed dose combinations for drugs falling under the definition as new drugs approved by the Licensing Authority. No Rules/Guidelines on suitable and uniform administrative action on violations like Sale without prescription, Sale without bill, Absence of pharmacist, Not of Standard Quality Drugs, Grossly substandard drug (potent drug and drug having dosage less than 10 mg), GMP violations (Major/Minor/Critical). Duplication of regulatory work at Centre and state without compromising the safety,

efficacy and quality of drugs, devices and cosmetics. Each State has different Structural and Administrative set up in their organization.

CONCLUSIONS

Uniformity in administrative actions taken by the state authorities. Uniform nationwide standard operating procedure for the enforcement officers is required for conducting investigations into spurious, sub-standard and Misbranded drugs. Avoid duplication of regulatory work at Centre and state without compromising the safety, efficacy and quality of drugs, devices and cosmetics. Rules/Guidelines on suitable and uniform administrative action on violations like. Sale without prescription, Sale without bill, Absence of pharmacist Not of Standard Quality and Grossly substandard Drugs. Good Manufacturing Practices Violation violations (Major/Minor/Critical). Uniformity in administrative actions taken by different state authorities. Fixed dose combinations for drugs failing under the definition as new drugs to be approved by the Licensing Authority. Uniform nationwide standard operating procedure for drug inspectors conducting investigations into sub-standard drugs thereby leading to a significant difference in the manner in which cases are prosecuted in different parts of the country.

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CONFLICTS OF INTEREST

We the Authors declare that there are no conflicts of interest.

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