

Drugs Regulation in Puducherry : A Overview

Kempaiah Suresh and Balamuralidhara V.

Department of Pharmaceutics, JSS College of Pharmacy, JSS University, Sri Shivarathreeswara Nagara, Mysore – 570 015, Karnataka, India.

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ABSTRACT

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. Drugs Control Department is independent of the Health Department and the Heads of these Departments are reporting to the Government directly. The State of Puducherry has some of the country's most dynamic entrepreneurs who are original and fast-paced in their thinking and focused in their drive for growth and profitability. Puducherry is one of the most industrialised states with 10 Manufacturing units are WHO GMP certified. Puducherry is one of the fastest growing states in the Country and nearly 105 pharma companies are housed in the State. Puducherry is a vibrant pharmaceutical manufacturing hub with skilled human resource available in the state, it provides innovative, quality and affordable health care solution to masses. In this short review author provides some of the glimpses of the pharmacy profession in Puducherry.

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Introduction



Puducherry

➤ Puducherry, the former French colony Settled in the early 18th Century, is a Charming Indian town with a few enduring Pockets of French Culture, and an Ashram set beside the sea. Puducherry is a Union Territory with Legislature extending over an area of 479 Sq .kms. Comprising of four regions and two districts viz Puducherry and Karaikal. Puducherry District comprising of Puducherry, Mahe and Yanam. There are 5 Municipalities and 10 commune Panchayats total population of UT is 9, 46, 600 as per 2011 censuses. There are 45 Large scale 132 Medium scale and 8326 Small scale Industries in the union territory of puducherry. Puducherry is a Town in Puducherry Tehsil in Puducherry District in Puducherry State. Puducherry is Main Town for the Puducherry Tehsil. Puducherry Is Main City for the Puducherry District It is located 4 km distance from its State Main City Puducherry.¹

➤ Food and Drugs Administration Puducherry

➤ History

➤ The Food and Drugs Administration is functioning as one of the unit of the Health Department under the control of Director of Health and Family Welfare Services who has been notified as Commissioner of Food and Drugs Administration for the purpose of the Drugs and Cosmetics Act, 1940 and Prevention of Food Adulteration Act, 1945 there has been enormous growth in the field of Drugs Manufacturing Units and Drugs Sales Units, with a meager capacity of manpower in the Food and Drugs Administration unit, this Administration is unable to perform proper statutory functions like enforcement of the Drugs and Cosmetics Act with the increase in the number of pharmaceutical industrial units, sales units and complaints thereon like adulterated drugs, non-quality of drugs and expired drugs moving in the market. At one stage, the continuance of the Director of Medical Services as Licensing Authority under the Drugs and Cosmetics Rules, 1945 was legally challenged under the provisions of the Drugs and Cosmetics Rules, 1945 since he did not possess the qualifications as prescribed under rule 49(A) of the Drugs and Cosmetics Rules, 1945. As per the court direction, the appointment of a qualified person as Licensing Authority has been carried out, but delinking of Food and Drugs Administration from the Directorate of Health and Family Welfare Services was under consideration of the Government since long back.

➤ The Directorate and other subordinate institutions of the Health Department is purchasing drugs for the purpose of storage and distribution of the medicines at free cost to the poor and at a price for others. The Health Department along with subordinate institutions is involved in the purchase and sale of drugs to the patients. Hence, delinking of Drugs Administration from the Health Department, which has direct and indirect interest in the sale of drugs is only legal necessity as per the Act. In other states like Tamil Nadu, Andhra Pradesh, Karnataka and Kerala, Drugs Control Department is independent of the Health Department and the Heads of these Departments are reporting to the Government directly.

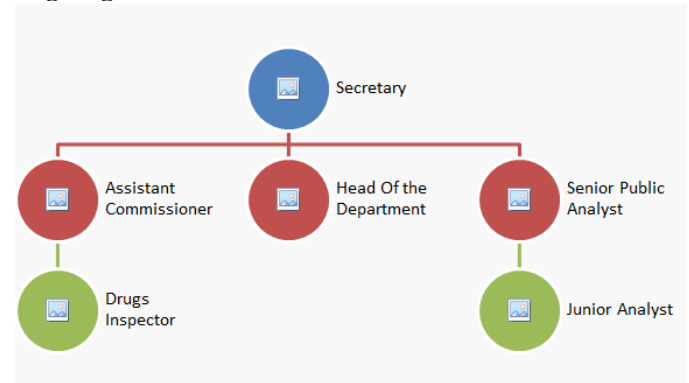
➤ As such, it is decided to delink the Drugs Administration from the Health Department and to set up a separate Directorate in order to streamline and strengthen the Drugs Administration. Whereas, the Government of India has taken a corrective measure in food safety structure and the status of Food Testing Laboratory in the States and accordingly the Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 with the mandate to lay down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption. As instructed by the Government of India to all the State Governments/Union Territories, a separate Department of Food Safety is to be constituted for which a Senior Secretary Level Officer will be the Apex of the Food Authority and should have independent authority over the Food Licensing Authority, Food Safety Officers and Food Testing Laboratory. Under section 30 of the Food Safety and Standards Act, 2006, State will appoint a Food Safety Commissioner preferably not below the rank of Joint Secretary to Government of India. Under Food Safety Commissioner, there should be a cadre of Food Safety Officers/Designated Officers/Adjudicating Officers and

Food Analysts. As such, it is decided to set up a separate Department of Food Safety in the Union territory of Puducherry. Whereas, the Government of India have also analysed the status of Food Testing Laboratory of States/ Union Territories and availability of qualified Food Analyst and technical personnel; Under section 43 of the Food Safety and Standards Act, 2006, every food testing laboratories and research institutions should be accredited by National Accreditation Board for testing and Calibration Laboratories or any other accreditation agency for the purpose of carrying out analysis of samples by the Food Analyst under this Act. In the Union territory of Puducherry, there is a Food and Drugs Testing Lab. which is functioning under the control of Directorate of Health and Family Welfare Services. But this laboratory is yet to be issued with accreditation certificate from the National Accreditation Board.

➤ Drug Testing Lab:

• The Public Health Laboratory is a multifaceted Scientific Institution, started functioning since 1972, under the Health Department. It is consisting of different analytical sections such as Food Testing Lab, Drug Testing Lab, Forensic Lab, Excise Lab, Water Testing Lab and Clinical samples analysis Lab. 3 a total of 163 samples of drugs like I.V. Fluids, Antibiotics, single components drugs have been tested with conformity to that different Pharmacopeia and Drugs and Cosmetics Acts. The Lab is headed by Senior Public Analyst under them Junior Analyst are working. As such, it is decided to set up a full-fledged and combined Food and Drugs Laboratory in the Government of Puducherry for Food and Drugs Analysis as existing in other States. Accordingly, His Excellency the Lieutenant-Governor is pleased to approve the delinking/setting up of three separate Departments for Drugs Control, Food Safety, Food and Drugs Testing under the control of Secretary to Government (Health) with the following organizational set up.

Organogram



➤ Statutory Authorities and their Functions

- Secretary to Government (Health)-cum Food Safety Commissioner
- Drugs Controller (Controlling Authority) under Drugs and Cosmetics Act, 1940
- Deputy Food Safety Commissioner (Controlling Authority) under Food Safety and Standards Act, 2006
- Senior Public Analyst (Food) and Government Analyst (Drugs) (Food and Drugs Testing Laboratory)
- Assistant Drugs Controller (Licensing Authority)
- Senior Food Safety Officer/ Designated Officer
- Bio-Chemist/Public Analyst/ Bacteriologist/Junior Scientific Officer/Manufacturing Chemist Drugs Inspector by Direct Recruitment
- Food Safety Officer
- Senior Scientific Assistant Technical Assistant/Senior Lab. Technician

➤ Consequently, the Lieutenant-Governor is pleased to order that :—

- The Secretary to Government (Health) will be the Head of Department and the Administrative Secretary in respect of the above three Departments.
- The Secretary to Government (Health) will act as the Food Safety Commissioner of the Union territory of Puducherry.
- The Department of Drugs Control, Department of Food Safety and Department of Food and Drugs Testing (erstwhile Public Health Laboratory) will be headed by the Drugs Controller, Deputy Food Safety Commissioner and Senior Public Analyst respectively.
- The Drugs Controller, Deputy Food Safety Commissioner and Senior Public Analyst will be the Head of Offices in respect of the officers/staff under their control in all the four regions. They will also be Drawing and Disbursing Officers in their respective departments in respect of Puducherry region and the seniormost officers working in the Karaikal, Mahe and Yanam regions will be the Drawing and Disbursing Officers in respect of the units of the department concerned functioning in the respective regions.
- The officers/staff of each department will be under the control of the Drugs Controller, Deputy Food Safety Commissioner and Senior Public Analyst respectively.
- The statutory posts in respect of Drugs Control and Food Safety will be distributed to the four regions of the Union territory of Puducherry and in the respective jurisdiction of Municipal area as detailed below:—
- Drugs Control: (1) Assistant Drugs Controller. . 2 (Puducherry) 1 (Karaikal) 1 (Mahe and Yanam) (2) Drugs Inspector. . 4 (Puducherry i.e. Headquarter-1, Puducherry

Municipal area-1, Oulgaret Municipal area-1, Puducherry rural area-1) 2 (Karaikal) 1 (Mahe) 1 (Yanam)

• Food Safety: (1) Senior Food Safety Officer. . 2 (Puducherry) 1 (Karaikal) 1 (Mahe and Yanam). (2) Food Safety Officer. . 4 (Puducherry i.e. Headquarter-1, Puducherry Municipal area-1, Oulgaret Municipal area-1, Puducherry rural area-1) 2 (Karaikal) 1 (Mahe) 1 (Yanam)

• The new departments will start functioning independently in all respect with effect from the financial year 2011-2012. .

• The Lieutenant-Governor is also pleased to order that the Senior Public Analyst, Department of Food and Drugs Testing (Public Health Laboratory), Puducherry will hold additional charge of the Deputy Food Safety Commissioner till the post of Deputy Food Safety Commissioner is created and filled up.

• The Lieutenant-Governor is also pleased to order that the Controlling Authority (Drugs), will be the Head of Office till the post of Drugs Controller is created and filled up.^{2,3}

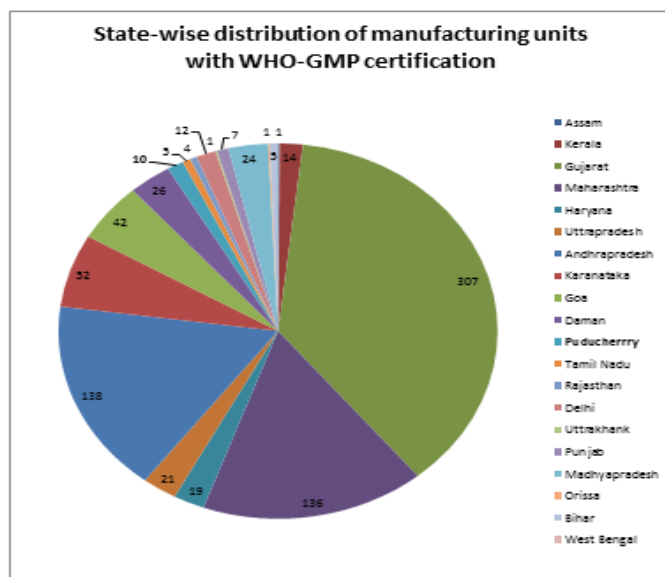
➤ Pharmaceutical Industry

• Puducherry has nearly 8708 small scale industries apart from 45 largescale and 80 medium scale industries. Taken together, these provide employment to more than 80,000 people. Some of the significant industries in Puducherry are chemicals, textiles, light engineering, metals, and food processing. Special mention needs to be made of the tourism sector in Puducherry.. As a result, Puducherry's investment opportunities are tremendous –hotels, resorts, amusement parks, and spas, all are lucrative sectors. The Indian government supports investment in Puducherry by increasing subsidies. Sectors like eco-tourism, footwear, and marine products are some of the areas where an investment boost is expected in Puducherry. Aurobindo is among India's top five pharma companies in the country. It commenced operations in 1988-89 with single unit manufacturing semi-synthetic penicillin's (SSPs) at Puducherry and is now a market leader. Shasun Pharmaceuticals Pvt. Ltd., #d Pharmaceuticlas, Orchid Chemicals and Pharmaceuticals Ltd., MSD pharmaceuticals Pvt. Ltd., Goodman Pharmaceuticals, Glaxo Smithkline Pharmaceuticals,

• There are about 105 Manufacturing units at Puducherry

• There are 650 Retailers and 100 wholesalers in Puducherry

• There are about 20 Blood Banks and 20 Blood storage centres in Puducherry.^{4,5}



Puducherry State Pharmacy Council

Puducherry Pharmacy Council is a State authority under the under the control of state government. Puducherry is situated in puducherry. In 1975 the Puducherry (earlier known as Pondicherry) Pharmacy Council was constituted. It was after a period of 35 years that the Government of Pondicherry reconstituted the Pharmacy Council with elected members. There are more than 1200 Registered Pharmacist registered in Puducherry. There is one Pharmacy college in Puducherry.⁶

Conclusion

The Manufacturing activity in Puducherry has witnessed tremendous expansion in last one decade. Puducherry has thousand two hundred pharmacists in the state. The entire spectrum of the pharmacy related activities in Puducherry are brought under one roof, i.e., drugs control administration, pharmacy education, pharmaceutical Industry and trade business establishment for all around the development of pharmacy.

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