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Drugs Regulation in Rajasthan: An Overview.

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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 Rajasthan 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. Rajasthan is one of the most industrialised states with 10 Manufacturing units are WHO GMP certified. Rajasthan is one of the fastest growing states in the Country and nearly 100pharma companies are housed in the State. Rajasthanhas agood enforcement 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 Regulation of Drugs in Rajasthan

Keywords: Pharmacy profession, Rajasthan, Health, Drug.

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INTRODUCTION

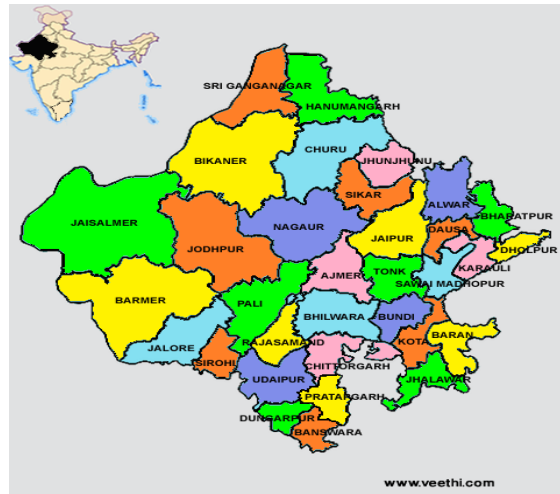


Figure 1: Rajasthan

Rajasthan literally, "Land of Kings")is India's largest state by area (342,239 square kilometres (132,139 sq mi) or 10.4% of India's total area). It is located on the western side of the country, where it comprises most of the wide and inhospitable Thar Desert (also known as the "Rajasthan Desert" and "Great Indian Desert") and shares a border with the Pakistani provinces of Punjab to the northwest and Sindh to the west, along the Sutlej-Indus river valley. Elsewhere it is bordered by five other Indian states: Punjab to the north; Haryana and Uttar Pradesh to the northeast; Madhya Pradesh to the southeast; and Gujarat to the southwest.

The state was formed on 30 March 1949 when Rajputana – the name adopted by the British Raj for its dependencies in the region was merged into the Dominion of India. Its capital and largest city is Jaipur, also known as Pink City, located on the state's eastern side. Other important cities are Jodhpur, Udaipur, Bikaner, Kota and Ajmer (Figure 1).[1]

Rajasthan Drugs Control Administration

The Department was established and started implementing Drugs and Cosmetics Act, 1940 and Rules, 1945 in Rajasthan state with effect from 16/07/1959.

The Government has notified Two Drugs Controller for the state for issue of licenses to manufacture and Distribution of Sale of Drugs.³⁵ The Assistant Drugs Controllers in all the Divisions were notified and designated as the Licensing Authorities. 115 Drugs Control Officer for the enforcement of the Acts. Thereafter over a period of time more number of Inspectors & Government Analysts has been appointed with ancillary staff for the implementation of the Act.(Figure2)

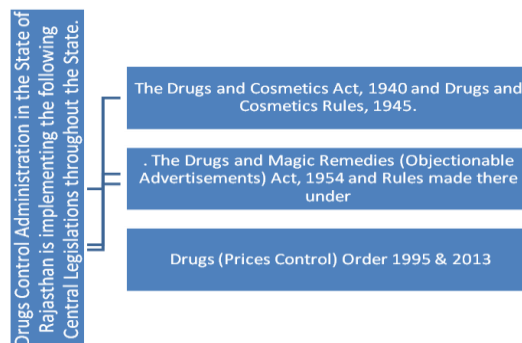


Figure 2

Drugs Control Administration is under the Ministry of Health and Family welfare in the Government of Rajasthan headed by the Drugs Controller who will be reporting to Government, Health and Family Welfare Department.

An Intelligence Wing is created and headed by the Assistant Drugs Controller having the state jurisdiction and main objective is to unearth Spurious / Adulterated / Misbranded Drugs, Cosmetics and to detect unlicensed dealers.

Head Office Functions

- Overall administration of the entire organisation
- Grant / renewal of Manufacturing licenses for Drugs & Cosmetics, Approval of laboratories, Blood Banks and Blood components, Blood Storage Centers,
- Approval to Recognized Medical Institutions for transport, possession and use of Oral Morphine for palliative care in cancer patients.
- Inspections of manufacturing units of Drugs, Cosmetics, Approved laboratories, Blood banks and Blood Storage Centers and medical devices.
- Investigation of complaints.
- Drawl of samples from manufacturing establishments
- Issue of certificates such as GMP (Good Manufacturing Practices) certificate, Free Sale Certificate, Tender purpose Certificate, Export Registration Certificate etc.,
- Overall administration of the entire organization.

Circle offices at District Level are headed by Assistant Drugs Controllers under whom Drugs control officers are working. They have been delegated the powers of Licensing Authority by Drugs Controller under Drugs and Cosmetics Rules, 1945 for the jurisdiction assigned to them.(Figure 3)

Functions

- Overall administration of the entire jurisdiction assigned
- They are over all in-charge of respective circle office
- Grant / Renewal of sales licenses
- Inspections of sales / manufacturing (wherever required) establishments, Government / Private hospital drug stores, Blood Banks & Blood Storage centers. Verifications are done at Retail firms whether drugs are sold under the supervision of registered pharmacist
- Drawl of samples from sales / manufacturing (wherever required) establishments / Drugs Stores attached to Govt. / pvt hospital for test and analysis
- Investigation of complaints
- Institution of prosecution against the defaulters & follow up
- Any other work assigned by higher ups.

Organizational set up

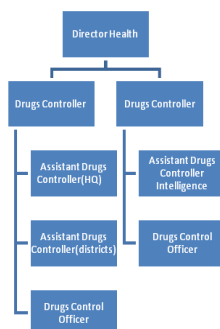


Figure 3

The Government of Rajasthan has introduced advanced single window clearance portal. The advanced portal provides a single window and time bound system for clearance and approvals. Granting of Retail and wholesale are attached to these services.[2]

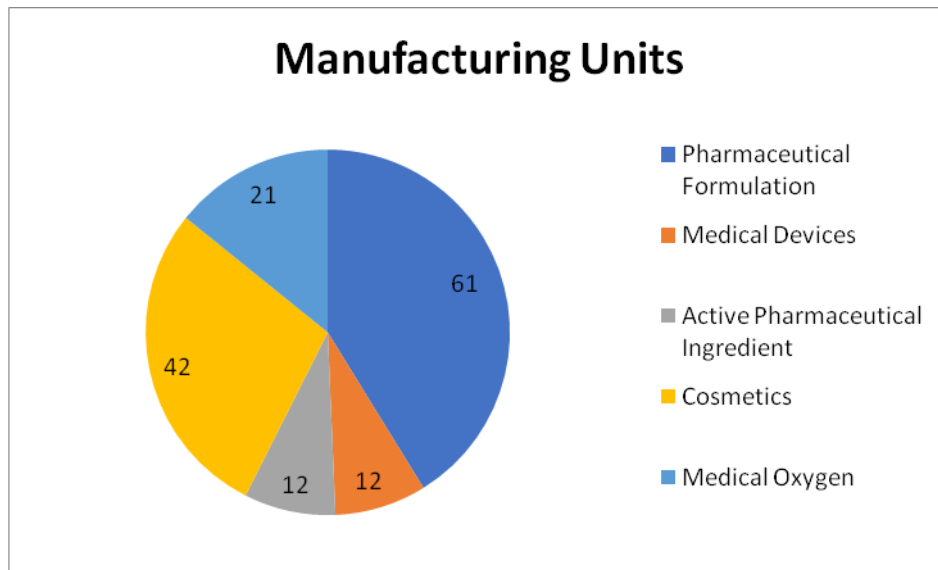


Figure 4

Manufacturing Unit Numbers are Pharmaceutical Formulations 61, Medical Device 12, Active Pharmaceutical Ingredient (API) 12, Cosmetics 42, Homoeopathic Medicines 8, Testing Laboratories 5, Medical Oxygen 21. There are about 235 manufacturing units in Rajasthan including Ayurvedic and Homeopathic. There are about more than 20000 retail and 16000 wholesale licences in the state of Rajasthan

There are about 52 Government blood banks and 51 private blood banks 123 blood storage centres

Rajasthan State Drug Control Department (RSCD) has already trained five drug inspectors for manning the price modulating cells in Rajasthan.

Drug inspectors have been trained on the Drug Price Control Order (DPCO-2013) regulation and the actions to be taken upon its violation. Training has also been given on how to conduct sample survey in the market of the respective drugs covered under and outside the DPCO. Drug inspectors are also technically equipped to implement modalities for recovery of the overcharged amount earned as a profit by manufacturer through overpricing of drugs.

The officials heading the cell will report their findings to the NPPA directly in case they find any pharma company violating the law by selling the drugs above the ceiling price.[3]

Drugs Testing Laboratory

There is only one drug testing laboratory in the state which is located at Jaipur. At present, the drug testing lab at Jaipur gets around 500 samples and testing of samples takes one month to three months time. Around 60,000 brands of drugs are available in the market and drug samples are collected based on the random survey. With the coming up of three state drug testing labs in Rajasthan, testing would be done in a mere 15 days time and the capacity would gradually increase over a period of time. The enhancement in the capacities will reduce the downtime significantly.

In order to enhance the capacity of sampling and testing of medicines in the state, three more drug testing laboratories will be established in Rajasthan at Udaipur, Jodhpur and Bikaner soon. The labs have been constructed and will now sooner be equipped with the state-of-the-art testing technologies and methods.

Currently

Following National Pharmaceutical Pricing Authority's (NPPA) proposed plan to set up price monitoring cells for effective detection of drug price violations in all the states three months ago.[4,5]

Rajasthan Pharmaceutical Industry

Rajasthan boasts of its pharma industry for providing high quality medicines on par with international standards. With a small number of 61 manufacturing units including Drugs and 12 Medical Devices, 12 Active pharmaceutical Ingredient(API) and 42 Cosmetics.

Rajasthan Pharma Industry comprises of small, medium and large scale, public sector and multinational companies & full-fledged, state-of-the art research and development laboratories with highly qualified, well-trained and competent human resource. Rajasthan Drugs & Pharmaceuticals Ltd (RDPL) is profit making Central Public Sector Enterprise. Company has started his commercial production in April 1981. Company has its Manufacturing Unit & registered office in VKI Area, Jaipur(Rajasthan). RDPL is a Government of India enterprise under the administrative control Department of Pharmaceuticals, Ministry of chemicals & fertilizers, Government of India. It is co- promoted by Government of Rajasthan (49%) through Rajasthan Industrial & Investment Corporation (RIICO). Company is schedule 'M' Compliant having manufacturing facility of Tablets, Capsules, Liquids , Powder & Ophthalmic.[6]

Rajasthan Pharmacy Council

Rajasthan Pharmacy Council is statutory body constituted under pharmacy Act, 1948. It was first constituted in 1978. It regulates the profession practice of pharmacy in the state of Rajasthan. There are more than 50 pharmacy colleges in the state imparting the pharmacy education. There are more than 40000 pharmacist in the state.[7]

CONCLUSION

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

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