

REGULATION OF DRUGS IN MADHYA PRADESH: AN OVERVIEW

KEMPAIAH SURESH¹, BALAMURALIDHARAN V²

¹Research Scholar, Regulatory Affairs Group, Department of Pharmaceutics, JSS College of Pharmacy, JSS University, Sri Shivarathreeshwara Nagar, Mysore, Karnataka, India

²Assistant Professor, Regulatory Affairs Group, Department of Pharmaceutics, JSS College of Pharmacy, JSS University, Sri Shivarathreeshwara Nagar, Mysore Karnataka, India

ABSTRACT

Madhya Pradesh has been one of the pioneer States in India with an exemplary track record in the overall field of Pharmacy. The Drugs Control Administration in India exists at two tier system the Central and State Government level. The Central Drug Control Standard Organization (CDSCO) is works in making policy, if laws and rules at all India level. It controls the licensing 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 and controls the new drug clearance, clinical trials, import registration, import of drugs etc., and inspections. Drugs Control Department in states deals with licensing of both manufacturing and sales establishments of Drugs & Cosmetics. Drugs Control Administration regulates the manufacture, sale and distribution of drugs to ensure their quality and efficacy. Madhya Pradesh is a pharmaceutical manufacturing hub fortified with sound knowledge based institutions and skilled human resource available in the state. It provides innovative, quality and affordable health care solution to the masses. In this short review author provides some of the glimpses of the Pharmacy and Regulation of Drugs in Madhya Pradesh.

KEYWORDS: *Pharmacy Regulation, Madhya Pradesh, Licensing Registration, Drug.*

INTRODUCTION

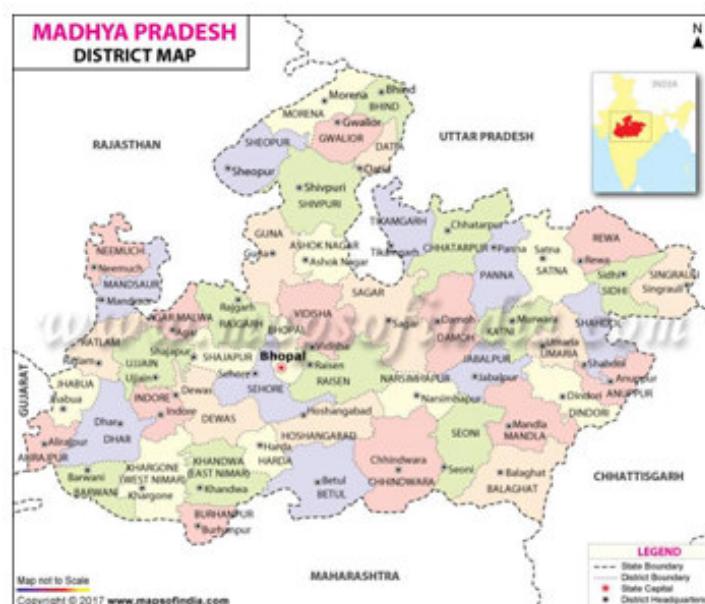


Figure 1 *Madhya Pradesh*

Madhya Pradesh (MP) is a state in central India. Its capital is Bhopal and the largest city is Indore. Nicknamed the "heart of India" due to its geographical location in India, Madhya Pradesh is the second-largest state in the country by area. With over 75 million inhabitants, it is the fifth-largest state in India by population. Madhya Pradesh, the second largest Indian State covering 9.5% of the country's area, is bestowed with rich natural resources, a wonderful climate and fertile agro-climatic conditions with a rich cultural heritage, an excellent quality of life, a flourishing industrial base, peaceful labour force, a progressive & investor friendly environment. It shares its borders with the states of Uttar Pradesh in the northeast, Chhattisgarh in the southeast, Maharashtra in the south, Gujarat in the west, and Rajasthan in the northwest. Its total area is 308,252 km². Before 2000, when Chhattisgarh was a part of Madhya Pradesh, it was the largest state in India and the distance between the two furthest points inside the state, Singoli and Konta, was 1500 km. The state has 51 districts.(Figure no.1)¹ Food and Drugs Administration Madhya Pradesh. Food and Drugs Administration Department works under the Public Health and Family Welfare Department, Government of Madhya Pradesh. The Department is under the Administrative supervision of Principal Secretary and is functioning under by the Honourable Minister of Public Health & Family Welfare Department. The Department started functioning from April 1st in the year 1979, before it was under the supervision of Directorate of

Health Services, M.P. Presently the organization is headed by the Commissioner, Food Safety and Controller, Food & Drugs Administration who is an I.A.S Officer.(Figure no.2)

Food and Drugs Administration in Madhya Pradesh has three Tier system

Enforcement Wing

Enforcement wing deals with licensing of Drugs / Cosmetics / Blood banks / Medical Devices manufacturing and sales establishments, inspections of manufacturing & sales establishments and drawing of samples for test and analysis, investigation of complaints, launching of prosecution against the defaulters etc.

It functions in a Two-tier system

- A. Head office
- B. Circle offices

And Level of Officers are

- Commissioner
- Joint Drugs Controller
- Deputy Drugs Controller/Deputy Director Food
- Senior Drugs Inspector/Senior Food Safety Officer
- Drugs Inspector/Food Safety Officer

The Joint Drugs Controller is the administrative and Establishment head. The Senior Drugs Inspector is the Licensing Authority for the Sales (5 years of experience) and Deputy Drugs Controller has delegated the Licensing Authority for Manufacturing to two Senior Drug Inspector.

Organisational Chart

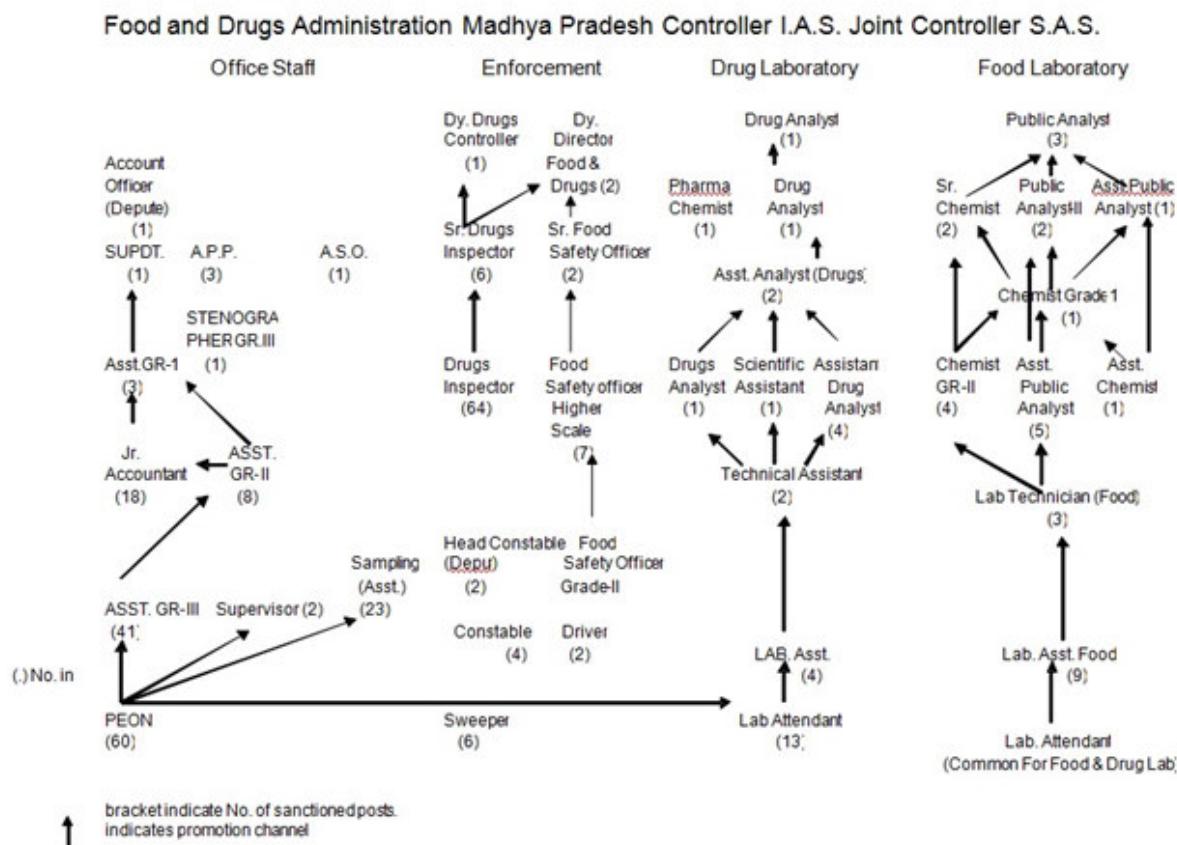


Figure 2
Organisational Chart

Implementation of Acts

- Enforcement of Drugs and Cosmetics Act, 1940 & Rules, 1945.
- Enforcement of Food Safety and Standard Act, 2006 & Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011.
- To ensure the quality in manufacturing, storage, sale & distribution of drugs, cosmetic & food articles.
- To issue the licenses/registration for manufacturing for sale, for distribution & storage of drugs / cosmetic & food articles.
- Enforcement of provisions of NDPS Act of pertaining to recognition of Medical Institutes to obtain essential narcotic drugs.
- To test /analyse the quality of product through Drugs Testing Laboratory and Food Testing Laboratory.

Food and Drugs Testing Laboratories

- A Full-fledged Drugs Testing Laboratory is functioning under the administrative control of the Commissioner. The DTL is fully equipped to undertake analysis of all categories of drugs except Vaccines, Sera,

Blood and Blood components and Diagnostic Kits. To ensure that only good quality drugs /cosmetics reach the common people the samples of these are routinely drawn by the Drugs Inspectors of this Administration which are sent to State Drugs Testing Laboratory. To ensure that only good quality food articles reach the common people, the samples of these are routinely drawn by the Food Safety Officers of this Administration which are sent to State Food Testing Laboratory accordingly.

- The DTL in Madhya Pradesh is headed by Senior Government Analyst. Each section is headed by a Government Analyst who supervises the work of Assistant Drug Analyst and Supporting staff (Technical and Non-Technical).

Total Licences In Madhya Pradesh

- List of Licensed Blood Banks Government Blood Banks – 53 and 6 Government of India (Public undertaking)
- There are 83 Private Blood Banks
- Blood Storage Centres – 69

- There are about 268 Manufacturing Licenses in the state ^{2,3}[Figure no.3]
- There are about 27000 Retail and wholesale firm in Madhya Pradesh

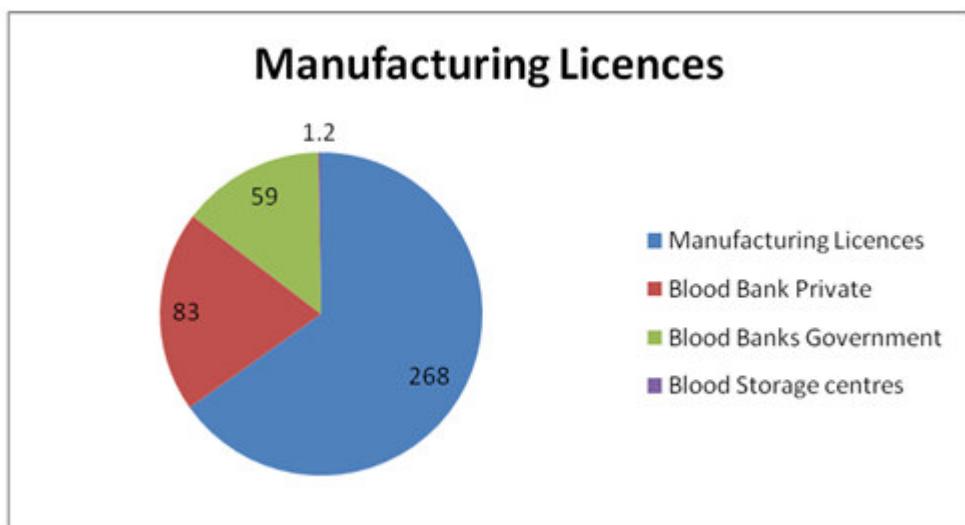


Figure 3
Manufacturing Licences

Madhya Pradesh Pharmaceutical Industry

- Madhya Pradesh with the presence of companies like Novartis, Teva, AkzoNobel, Cipla, Sun Pharma, Glenmark, Lupin and Piramal Healthcare, Madhya Pradesh has emerged as the major pharmaceuticals manufacturing destination in the country
- More than 250 pharmaceutical units are operating in industrial areas of Dewas, Indore, Pithampur, Mandideep and Malanpur
- Around 200 Ayurvedic and 50 Homeopathic medicine units are present in the state⁴
- In the map of Asia Indore is known as one of the largest producers of pharmaceuticals like basic drug formulations, tableting, Capsuling etc. There are numerous small and big pharmaceutical units like, Plethico, Penjon, Ranbaxy, Syncrom Formulations and Parental Drugs etc., are located in and around Indore. Indore is an industrial city, where a big number of large medium and small-scale industries are located. Other than Indore Industrial areas, Ujjain, Dewas, Dhar, also having their Industrial areas. Pithampur Industrial area of Dhar district is near Indore.

Pharmaceutical units in Indore can be divided into two groups: Allopathic formulations and Ayurvedic Formulations. At present about 350 pharmaceutical units in Indore are manufacturing the following items:

- Tablets
- Liquids Both in Allopathy&Ayurvedic Formulations
- Capsules

- IV .Fluids
- Eye Drops Allopathic Formulations
- Ointments.

Many units of the cluster are exporting their formulations to various countries directly or indirectly; most of the units are dependent on the local or domestic market.^{4,5}

Madhya Pradesh State Pharmacy Council

- The Pharmacy Act was enacted in the year 1948 to regulate the Profession & Practice of Pharmacy. The Pharmacy Council of India constituted under the Act for framing and implementing Education Regulations for minimum qualification required under the Act for a person to get himself/herself registered as a Pharmacist. The Pharmacy Council of India after due inspection gives approval to institutions which conduct course of Diploma in Pharmacy or Degree in Pharmacy. The Act provides for the constitution of State Pharmacy councils for the maintenance of Registers of Qualified Pharmacists and to prohibit the dispensing of medicine on the prescription of Medical Practitioner by the persons other than Registered Pharmacists. Madhya Pradesh Pharmacy Council, Bhopal Madhya Pradesh is a State Authority under the control of State Government. There are 45759 Registered in Madhya Pradesh state pharmacy council⁶
- There are about 100 pharmacy colleges in the Madhya Pradesh⁷

CONCLUSION

The Drugs Control Administration and Manufacturing activity in Madhya Pradesh has witnessed tremendous expansion in the last one decade. Madhya Pradesh had two hundred thirty sixty pharmacists in 1956 and this number has increased to eighty six thousand at present. The state was adopting a different procedure for issuing licence for manufacture and sale of drugs among states of India, which was not very effective. Hence there was a need for the amendment in the implementation of Drugs and Cosmetics Act 1940 and Rules 1945 among the States of India. The entire spectrum of the pharmacy related activities in Madhya Pradesh have been brought under one roof,

REFERENCES

- 1) Information on Madhya Pradesh - Wikipedia https://en.wikipedia.org/wiki/Madhya_Pradesh Accessed on 06 May 2017
- 2) Information of Madhya Pradesh Drugs control Administration available at <http://cfidamp.nic.in/contactus.aspx> Accessed on 25 April 2017
- 3) Information on Madhya Pradesh Food and Drugs Administration available at CFDA - controller, Food & Drugs Administration, MP <http://cfidamp.nic.in/> Accessed on 05 April 2017
- 4) Information on Pharmaceutical Industry available at Pharmaceuticals- Invest Madhya

i.e., drugs control administration, pharmacy education, pharmaceutical Industry and trade business establishment for all around the development of pharmacy.

ACKNOWLEDGEMENT

I would like to thank Sri Shobit FDA Madhya Pradesh, for providing the information that was needed to get this manuscript ready in the best possible manner.

CONFLICTS OF INTEREST

Conflicts of interest declared none.

pradesh| Global..available at www.investmp.com/pharmaceuticals Accessed on 05 April 2017

- 5) Diagnostic study report pharmaceutical cluster at [indore\(Madhyapradesh\).nic.in/Doc/cluster/cluster_indore.pdf](http://indore(Madhyapradesh).nic.in/Doc/cluster/cluster_indore.pdf) Accessed on 26 June 2017
- 6) Pharmacy Council <https://pharmacy.mponline.gov.in/portal/services/pharmacy/index.aspx> Accessed on 30 June/2017
- 7) State Pharmacy Councils <http://pci.nic.in/GeneralInformation/StatePharmacyCouncils.aspx> Accessed on 30 June 2017