Manual 1- Particulars of Organization, Functions and Duties

2.1 Objective/purpose of the public Authority:

The objective of the Drugs Control Department is to enforce the provisions of the Drugs and Cosmetics Act and Rules made there under, the Drugs and Magic remedies(Objectionable advertisement)) Act and Rules made there under, and the Drugs Prices Control order.

2.2 Mission/Vision Statement of the public authority

To ensure that public gets drugs and cosmetics of standard quality at the prices fixed by the concerned authority and the public is not misled by advertisement for prevention/mitigation or cure of certain diseases or disorders.

2.3 Brief history of the public authority and context of its formation.

Drugs are necessary to save life or to restore or preserve health. It is, therefore, imperative to ensure that the consumers receive drugs of quality and at reasonable price. The genesis of Drug Control in India could be traced back to pre independent era, when India was largely dependent on import of modern drugs. As a result of chaos, the Indian market was flooded with the adulterated, substandard or spurious drugs. In 1927, a Resolution was adopted by the Council of States recommending to the Governor-General in Council to urge all Provincial Governments to take immediate steps to control the indiscriminate use of drugs and to legislate for the standardization of the preparation and sale of such drugs. In August, 1930 in response to public opinion against defective drugs and in pursuance of the Resolution of 1927, Government of India appointed a Committee known as Drugs Enquiry Committee with Colonel R.N.Chopra as its chairman to go into the question of adulterated and substandard drugs sold in the country and to recommend steps by which this menace could be controlled. The Committee in its report submitted in 1931, recommended to make a central legislation to control drugs. As a result of this report, Government of India enacted Drugs Act in 1940 which provides for regulation of import of drugs into India and manufacture, sale and distribution of drugs in the country. The Drugs Rules were framed in 1945 to give effect to the provisions of the Act.

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Regulation of import of drugs is the responsibility of the Central Government whereas licensing of manufacture, sale and distribution of drugs in the country is the responsibility of the State Governments but their enforcement is governed both by central as well state governments.

2.4 Duties of the public authority

a. Grant/renewal of licences for the manufacture of drugs and cosmetics
b. Grant/renewal of permission to manufacture additional items of drugs and cosmetics
c. Grant/renewal of licences for sale of drugs/Homeopathic medicines.
d. Investigation of complaints regarding offences under Drugs and Cosmetics Act/rules, Drugs and Magic Remedies Acts/rules and Drugs Prices Control order.
e. Launching prosecution against the offenders of the above mentioned statutes when the offence can have serious consequences.

2.5 Main activities/functions of the public authority.

Drugs control department of Delhi State is an independent department and is enforcing the provisions of the following statues, enacted by Government of India throughout the State:-

A. Drugs and Cosmetic Act 1940 and Rules 1945.
B. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954,
C. Drugs (Price Control) Order 1995 made under the Essential Commodities Act 1955

These statues aim at ensuring the supply of quality drugs at reasonable prices to the needy and safe guarding the unwary public from misleading advertisements of drugs and drug abuse.

2.5.1 Enforcement of Drugs and Cosmetic Act 1940 and Rules 1945 made there under,

The main activities of the department under this statues are as under :

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1. **Licensing work:**
    a. Licensing of manufacturing premises for
        i. manufacture of Drugs including Repacking of Drugs & Surgical Dressings.
        ii. operation of Blood Centres
        iii. manufacture of Homeopathic Medicines.
        iv. manufacture of Cosmetics.
        v. approval of Testing Laboratories
    b. Licensing for sales premises for
        i. retail sale/wholesale/restricted sales of drugs.
        ii. retail sale/wholesale of Homeopathic Medicines.
2. **Inspection Work**

    a. Inspection of manufacturing & sales premises

        i. for grant or renewal of manufacturing and sale licences
        ii. to check compliance with conditions of licences, and
        iii. to check compliance with the provisions of the Drugs & Cosmetics Act & Rules.
    b. Inspections of hospitals and dispensaries to ensure compliance of the provision of Drugs & Cosmetics Act & Rules.
    c. Intensive/in-depth inspections and raids for the detection of:
        i. Sub-standard/spurious drugs & cosmetics.
        ii. Unlicensed premises.
        iii. Unauthorized movements of drugs.
    d. Investigation of complaints.
    e. Enquiries regarding quality of drugs

3. **Sample work.**

    Collection of samples of drugs and cosmetics from manufacturing and sale premises and hospitals and dispensaries for test and analysis to ensure their quality.

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4. **Investigations & Prosecutions**

a. Investigations regarding offences committed under the Act with a view to collect necessary evidence.
b. To launch prosecutions against persons / firms found contravening the provisions of the Act and to conduct cases in court of law.

2.5.2 Enforcement of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954

Under this Act various advertisements published in newspapers , periodicals and journals are scrutinized for objectionable advertisements and investigations are carried out in those cases where contraventions are observed. Prosecutions are launched under the Act against the persons found publishing such objectionable advertisements.

2.5.3 Enforcement of Drugs (Prices Control) Order 1995, made under Essential Commodities Act, 1955

Under this Order, the sales premises are checked to ensure that drugs are sold at a price not exceeding maximum retail price and investigations are carried out in those cases where violation of the Order are observed and prosecutions are launched under the Act against such persons.

2.5.4 Miscellaneous Work

i. allocation of narcotic drugs
ii. issue of duty free indent for spirituous preparations.
iii. advising Excise & Custom Departments on matters related to drugs.
iv. liaison with other State Drugs Controllers and Police etc.
v. to carry out surveys for finding out availability of essential drugs in the market and to communicate the details of shortage, if any, to the National Pharmaceuticals and Pricing Authority under Ministry of Chemicals & Fertilizers, Government of India, every month.

2.6 List of services being provided by the public authority with a brief write-up on them.

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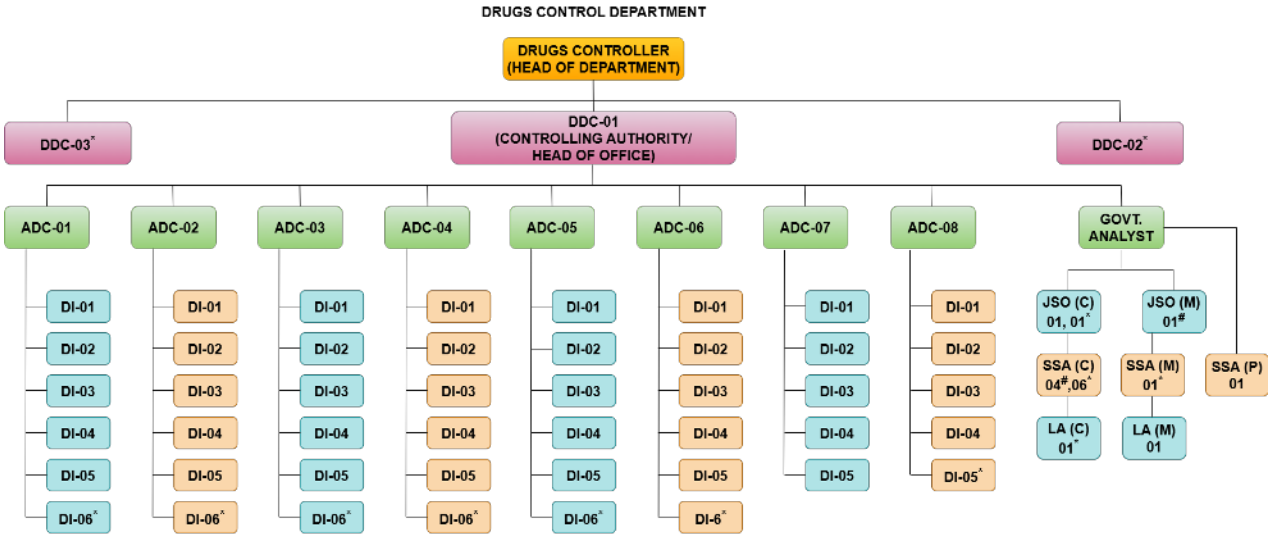
The department basically is an enforcement department, however, it grants licences under the Drugs and Cosmetics Rules. The category of licences which are issued by the department are as under:-

i. Grant/renewal of licences to manufacture drugs/homeopathic medicines.
ii. Grant/renewal of manufacturing licences for cosmetics.
iii. Grant/renewal of licences for sale of Drugs/homeopathic medicines.
iv. Grant of permission to manufacturer additional items of Drugs/Homeopathic medicines.
v. Grant of permission to manufacture additional items of cosmetics.

2.7 ORGANISATIONAL STRUCTURE OF DRUGS CONTROL DEPARTMENT



DDC: Deputy Drugs Controller
ADC: Assistant Drugs Controller
DI: Drugs Inspector
JSO (C): Junior Scientific Officer (Chemistry)
JSO (M): Junior Scientific Officer (Microbiology)
SSA (C): Senior Scientific Assistant (Chemistry)
SSA (M): Senior Scientific Assistant (Microbiology)
SSA (P): Senior Scientific Assistant (Pharmacology)
LA (C): Laboratory Assistant (Chemistry)
LA (M): Laboratory Assistant (Microbiology)
*: Vacant
#: Filled with Contract

2.8 Expectation of the public authority from the public for enhancing its effectiveness and efficiency.

No law can be enforced unless the stake holders co-operate with the enforcement agency. Public in particular, therefore, the drug control department will expect the public to give information about any suspicious activity regarding manufacture/sale of drugs, overcharging in the prices of drugs.

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2.9 Arrangements and methods made for seeking public participation/ contribution.

The department arranges meetings with drug manufacturers located at Delhi and also with the associations of chemists, time to time, either on the request of the associations or on its own. During these meetings the enforcement problems or other problems of the working of the department are discussed and decisions are taken with consensus.

2.10 Mechanism available for monitoring the service delivery and public grievance resolution.

The department has devised a feed-back form. The feed-back form is available with the Drugs Inspector, Headquarters. The form is also available at the dispatch counter where licences are issued and the form has been displayed at the notice board. The feed back forms received from the public are screened for their comments.

If there is any delay in the processing of applications for grant of licences, applicant may contact Assistant Drugs Controller of respective area in case of licences for sale of drugs. In case of other grievances the public may contact the designated Public Grievance Redressal Officer. The telephone numbers and time at which the public can meet these officers has been mentioned in the Citizens Charter. The Citizens Charter is available at the reception counter of the department as well as with the Drugs Inspector, Headquarter.

2.11 Address of the main office:

Drugs Control Department,
IVth Floor, 17-Karkardooma, Shahdara, Delhi.

Address of the zonal office:

Drugs Control Department,
A-20, Lawrence Road Industrial Area, Delhi.

2.12 Working hours of the office: 9.30 a.m. - 6:00 p.m.

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