

Chapter – 7

DRUGS CONTROL ADMINISTRATION

7.1. The Drugs Control Administration has the prime object of enforcement of the following enactments for regulating the Manufacture, Distribution and Sale of Drugs and Cosmetics:-

- a) Drugs and Cosmetics Act 1940 and Rules 1945
- b) Drugs Prices Control Order 1995
- c) Drugs and Magic Remedies (Objectionable Advertisement) Act 1954.

The officers of this Department are also empowered to act under Narcotic Drugs and Psychotropic Substances Act, 1985. The Director of Drugs Control is the Controlling and Licensing Authority for grant and renewal of licences for manufacture and sale of Allopathic, Ayurveda, Siddha, Unani Drugs, Homeopathic Medicines and Cosmetics and also Licensing Authority for Blood Banks in Tamil Nadu along with the Central Licence Approving Authority.

7.2. **Functioning of Mobile Squad and Legal-cum-Intelligence Wing:**

There is a Mobile Squad at Madurai as its headquarters and a Legal-cum-Intelligence Wing in this Directorate to attend complaints relating to Spurious Drugs and to investigate specific complaints in Southern Region and in Chennai respectively. Apart from this work, the Legal-cum-Intelligence Wing processes Legal matters and undertakes special investigations.

7.3. **Drugs Testing Laboratory:**

There is a full fledged Drugs Testing Laboratory attached to this Department which undertakes testing of samples, drawn by the Drugs Inspectors (other than Parenteral Preparations) from various Retail, Wholesale Units, Manufacturing Units and Hospitals, Government as well as Private Hospitals. The Parenteral Preparations are tested at King Institute of Preventive Medicine at Guindy.

7.4. **Achievements during 2007-2008:**

7.4.1. **Drug Information and Pharmaco Vigilance Centre:**

Drug is an important commodity in the day to day life of the common man. But unlike other items consumed by them, they are unaware of the nature and usefulness of the drugs. For the other item of day to day use, they confirm its usefulness and worthiness before purchasing them. But for drugs, there is no choice, except to purchase what is prescribed.

The Physicians or Surgeons prescribe the medicine and they do not have time to give the full details about the drugs to the Patient. The Pharmacists in the dispensaries are also not having adequate time to give the complete details of the drugs prescribed by the Doctors. The Drug Regulatory officials who are less in number are always occupied with other works. Hence, to overcome the problems or difficulties of the common man especially poor in getting information about the drugs, method of usage i.e. its Dosage, Safety, Precaution and time and methods of intake, a Drug Information and Pharmaco Vigilance Centre has been created. This centre shall function from 10.00 a.m to 5.00 p.m initially on all working days and later on depending on the demand from the public, the working hours will be increased. This centre can be used by Doctors and other Professionals in getting any information relevant to them within half an hour. But in cases where it requires collection of relevant materials from other sources, reply will be given by the next day after getting the contact phone number or Email I.D. or by post. This centre is provided with all facilities like Broadband connection with computers to access internet and with all other accessories. This

centre will be operated by one Pharmacologist with M.Pharm Qualification and one with Graduate in Pharmacy and one with Diploma in Pharmacy. This is a joint venture of Directorate of Drugs Control and Tamil Nadu Pharmacy Council. This center has following E mail ID:

tndruginfo@gmail.com
tndruginfo@yahoo.com
Phone No: 044 - 2433 8421

This centre will also receive information from general public, Hospitals and others about any adverse effect on any drug which they have consumed and this data will be collected and used for future studies on the nature of the drug so that if any abnormal incidence of Toxic effect is reported, corrective steps can be taken.

7.4.2. Handycam for the use of Zonal Offices, Mobile Squad at Madurai and Intelligence Wing in the Office of the Director of Drugs Control, Chennai have been purchased at a cost of Rs. 2.25 Lakhs.

7.4.3. LAPTOP and LCD Projector for Seminar Hall in the Office of the Director of Drugs Control, Chennai have been purchased at a cost of Rs.1.35 lakhs.

7.4.4. On information that drug I-Pill (Emergency Contraceptive pill) and Levonorgestral Tablets B.P.1.5 mg, manufactured by M/s. Cipla Ltd., Goa, contravene the provision of Drugs and Cosmetics Act 1940 and Drugs and Magic Remedies (Objectionable Advertisement) Act 1954, a Joint inspection was conducted at the Depot of the firm and seized drugs worth Rs.1,98,750/-. Legal action is being initiated against the marketer for the contravention of Section 18 of the Drugs and Cosmetics Act 1940 & rules 1945 there under and Drugs and Magic Remedies (Objectionable Advertisement) Act 1954.

7.4.5. On information that the drug Preventol Tablets (Emergency oral Contraceptive Pills) manufactured by M/s.Hindustan Latex India Ltd., Karnataka, contravene the provision of Drugs and Magic Remedies (Objectionable Advertisement) Act 1954, a Joint inspection by the Drugs Inspectors of this Department was conducted and legal action is being initiated for the contravention under Drugs and Magic Remedies (Objectionable Advertisement) Act,1954.

7.4.6. Other legal actions initiated against manufacturers and dealers:

A total of 242 Prosecutions have been sanctioned for the period from 01.04.2007 to 31.03.2008. The following are the major contraventions for which sanction has been accorded:-

- (i) Two (2) sanction for prosecution has been accorded under Drugs and Magic Remedies (Objectionable Advertisement) Act 1954.
- (ii) Fifty Four (54) sanctions for prosecution have been accorded for having manufactured for sale of Not of Standard Quality Drugs, Spurious Drugs and Adulterated Drugs against different manufacturers.
- (iii) One hundred and Eighty four (184) sanctions have been accorded for other contraventions under Drugs and Cosmetics Act,1940.
- (iv) Two (2) sanction has been accorded under Drugs Price Control Order.

7.5. New Schemes for the year 2008-09:

1. Provision of Lift facilities to the Office of the Director of Drugs Control, at a cost of Rs.20 Lakhs.
2. Provision of one Direct Telephone Line for augmentation of Net facilities and for changing the existing EPABX Board to the Office of the Director of Drugs Control, at a cost of Rs. 0.80 Lakh.
3. Purchase of Reference Books for Administrative Office and Zonal Offices at a cost of Rs.2.00 Lakhs.
4. Purchase of New Instruments/Equipments to replace the old and outdated Instruments / Equipments for the use of Drugs Testing Laboratory, at a cost of Rs. 50 Lakhs.
5. Purchase of Computers for the use of Drugs Testing Laboratory, at a cost of Rs.2 Lakhs.
6. Installation of LPG cylinders in Drugs Testing Laboratory, at a cost of Rs.0.25 Lakh.