Name of Unit	The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954
Subject /Course name	Pharmaceutical Jurisprudence
Subject/Course ID	BP 505T
Class: B.Pharm. Semester	V
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Learning Outcome of module 04

LO	Learning Outcome (LO)	Course Outcome Code
LO1	Discuss the objective, definition of drug and magic remedies act	BP505.6
LO2	Discuss the objective, definition of prevention of cruelty to animal act and guidelines of CPCSEA.	BP505.6
LO3	Explain the offences and penalties related to cruelty animal act.	BP505.6
LO4	Explain the objectives, definition of drug price control order.	BP505.6

Content Table

Topic
• Definitions, objective, Administration of the act and rules Drug and Magic Remedies Act. • Prevention of Cruelty to animal act 1960. • Guidelines of CPCSEA • Drug Price Control Order(DPCO). • Retail Price Formula • National list of essential medicines.

The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954

Contents

- Study of salient features of drugs and magic remedies act and rules, Schedule J.
- Classes of prohibited and exempted advertisements. Offences and penalties.

Intended Learning Outcomes

At the end of this lecture, the student will be able to:

- Explain the objectives of the act
- List the diseases that cannot be cured
- Explain prohibited and exemptted advertisements

Objectives

- The Drugs and magic remedies act came into force on 1st April 1955
- The objective is to prohibit certain kinds of advertisements relating to drugs and magic remedies which makefalse claims and are likely to mislead the public
- The prohibitions do not apply to the advertisements sent to medical practitioners or chemists or advertisementsmade on behalf of the governments
- The act extends to the whole of India except the state of Jammu and Kashmir

Definitions

1. Advertisements: are defined to include all notices, circulars, labels, wrappers or other documents and all documents and all announcements made orally or by means of producing or transmitting light, sound or smoke
2. 2. Drugs: include substances intended for the diagnosis , cure, mitigation, prevention or treatment of diseases in human beings or animals or for altering any structure or functions of the body of human beings or animals except food articles
3. 3. Magic remedies: includes talismans, mantras, kavachas and substances or charms of any kind which claim to possess miraculous powers of prevention or cure of diseases or of affecting or altering any of the functions of the bodies of human beings or animals

Prohibited advertisements

The following classes of advertisements are prohibited to be made under the act:

Advertisements relating to drugs , which are likely to lead to their use in the following ailments or

conditions:

The procurement of miscarriage in women or prevention of conception in women

Advertisements relating to drugs , which are likely to lead to their use in the following ailments or conditions:

The maintenance or improvement of the capacity of human beings for sexual pleasure;

The correction of menstrual disorder in women; or

The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in theSchedule J

Advertisements which directly or indirectly give false impression regarding the true character of the drug or make anyfalse claims for it or are otherwise false and deceptive

Advertisements relating to magic remedies claiming their efficacy for any of diseases listed in Sch J

Schedule j

The Schedule J of the Drugs and Cosmetics Act 1945 of India- contains a list of diseases and ailments which adrug may not claim to prevent or cure

Diseases and Ailments (by whatever Name described) which a Drug may not Purport to Prevent or Cure or Make Claims to Prevent or Cure

1. Appendicitis
2. Arteriosderosis
3. Blindness
4. Blood poisoning
5. Bright's disease
6. Cancer
7. Cataract
8. Deafness
9. Diabetes
10. Diseases and Disorders of brain
11. Diseases and Disorders of the optical system
12. Diseases and Disorders of the uterus
13. Disorders of menstrual flow
14. Disorders of the nervous system
15. Disorders of the prostatic gland
16. Dropsy
17. Epilepsy
18. Female diseases (in general)
19. Fevers (in general)
20. Fits
21. Form and structure of the female bust
22. Gall stones, kidney stones and bladder stones
23. Gangrene
24. Glaucoma
25. Goitre
26. Heart diseases
27. High/Low Blood Pressure
28. Hydrocele
29. Hysteria
30. Infantile paralysis
31. Insanity
32. Leprosy
33. Leucoderma
34. Lockjaw
35. Locomotor ataxia
36. Lupus
37. Nervous debility
38. Obesity
39. Paralysis
40. Plague
41. Pleurisy
42. Pneumonia
43. Rheumatism
44. Ruptures
45. Sexual impotence
46. Smallpox
47. Stature of persons
48. Sterility in women
49. Trachoma
50. Tuberculosis
51. Tumours
52. Typhoid fever
53. Ulcers of the gastro-intestinal tract
54. Venereal diseases, including syphilis, gonorrhoea, soft chancre, venereal granuloma and lympho granuloma.]

Exempted advertisements

- Sign boards or notices, displayed by the RMP on their premises indicating that treatment is undertaken for thediseases or disorders, advertisements relating to which are otherwise prohibited
- Book or treatises related to diseases, ailments- provided they are published from bonafide scientific or socialstandpoint
- Advertisements relating to drugs which are sent confidentially, in the prescribed manner, to RMP (with the label“ For the use of Registered Medical Practitioners”
- Advertisements relating to drugs printed or published by the govt. or by any other person, with the priorpermission of govt.
- Advertisement, labels or sets of instructions which are permitted under the D& C act

Penalties

- Imprisonment which may extend upto 6 months or a fine or both on first conviction
- Imprisonment upto one year or a fine or both on any subsequent conviction

The people at Andhashraddha Nirmoolan Samiti (ANS) have published some illustrations to further awareness on the recently passed Maharashtra Prevention and Eradication of Human Sacrifice and other Inhuman Evil and Aghori Practices and Black Magic Act,

Summary

The Drugs and magic remedies act came into force in 1955

The objective is to prohibit certain kinds of advertisements relating to drugs and magic remedies which makefalse claims and are likely to mislead the public

Prohibited advertisements: classes of advertisements that are prohibited

The Drugs and magic remedies act came into force in 1955

The objective is to prohibit certain kinds of advertisements relating to drugs and magic remedies which makefalse claims and are likely to mislead the public

Prohibited advertisements: classes of advertisements that are prohibited

Exempted advertisements: not prohibited provided they follow certain conditions

Prevention of Cruelty to Animals Act 1960

Contents

- Objectives, establishment, constitution and functions of Animal Welfare Board of India.
- CPSCEA guidelines. Procedures to be followed during animal experimentation. Offences and penalties

Learning objectives

At the end of this lecture, the student will be able to:

- Explain the objectives of the act
- Describe the constitution and functions of Animal Welfare Board of India
- Describe the constitution and functions of Animal experimentation committee

Short title, extent and commencement

- This Act may be called the Prevention of Cruelty to Animals Act, 1960.
- It extends to the whole of India except the State of Jammu and Kashmir. ,
- It shall come into force on such date as the Central Government may, by notification in the official Gazette, appoint, and different dates may be appointed for different States and for the different provisions contained in this Act.

Objectives of the act

To prevent the infliction of unnecessary pain or suffering on animals and for that purpose to amend the law relatingto the prevention of cruelty to animals

ANIMAL WELFARE BOARD OF INDIA

Purpose:

For the promotion of animal welfare generally and for the purpose of protecting animals from being subjected tounnecessary pain or suffering

The different acts under this board are

1. PCA (Slaughter House) Amendment Rules, 2010
2. Draft Aquarium Fish Breeding Rules, 2010
3. Draft Dog Breeding Rules 2010
4. Revised Draft Pet Shop Rules, 2010
5. Transport of Animals (Amendment) Rules, 2009

6. Draft Animal Welfare Act, 2011
7. Animal birth control(Dogs) Amendment Rules 2010

Constitution:

The Board shall consist of the following persons, namely:

- the Inspector General of Forests, Govt. of India, ex-officio,
- the Animal Husbandry Commissioner to the Govt. of India, ex-officio;
- two persons to represent respectively the Ministries of the Central Govt. dealing with Home Affairs and Education, tobe appointed by the Central Govt;
- 1 person to represent the Indian Board for Wild Life, to be appointed by the Central Government;
- 3 persons who, in the opinion of the Central Government, are or have been actively engaged in animal welfare work and are well-known humanitarians, to be nominated by the Central Government;)
- 1 person to represent such association of veterinary practitioners as in the opinion of the Central Government oughtto be represented on the Board, to be elected by that association in the prescribed manner;
- 2 persons to represent practitioners of modern and indigenous systems of medicine, to be nominated by the CentralGovernment;
- 1 person to represent each of such two municipal corporations as in the opinion of the Central Government ought to be represented on the Board, to be elected by each of the said corporations in the prescribed manner
- 1 person to represent each of such three organizations actively interested in animal welfare as in the opinion of theCentral Government ought to be represented on the Board, to be chosen by each of the said organizations in the prescribed manner;
- 1 person to represent each of such three societies dealing with prevention of cruelty to animal
- 3 persons to be nominated by the Central Government,
- 6 Members of Parliament, 4 to be elected by the House of the People (Lok Sabha) and two by the Council of States(Rajya Sabha).

- The Central Government shall nominate one of the members of the Board to be its Chairman and another member ofthe Board to be its Vice-Chairman.

Reconstitution of the Board

- The Board as reconstituted under sub-section (1) shall be reconstituted from time to time on the

expiration ofevery third year

- The new members shall hold office only for the unexpired portion of the term for which they would have heldoffice if such reconstitution had not been made
- Vacancies arising as a result of their ceasing to be Members of the Board shall be filled up as casual vacancies forthe remaining period of the term of the Board as so reconstituted

Term of office and conditions of service of Members of the Board

- The term of office of an ex-officio Member shall continue so long as he holds the office by virtue of which he issuch a Member;
- The term of office of a Member elected or chosen shall come to an end as soon as he ceases to be a Member ofthe body which elected him or in respect of which he was chosen;
- The term of office of a Member appointed, nominated, elected or chosen to fill a casual vacancy shall continue for the remainder of the term of office of the member in whose place he is appointed, nominated, elected or chosen;
- The Central Government may, at any time, remove for reasons to be recorded in writing a member from officeafter giving him a reasonable opportunity of showing cause against the proposed removal and any vacancy caused by such removal shall be treated as casual vacancy for the purpose

Functions of the Board

- To keep the law in force in, India for the prevention of cruelty to animals under constant study and advise theGovernment on the amendments to be undertaken in any such law from time to time;
- To advise the Central Government on the making of rules under this Act with a view to preventing unnecessary pain or suffering to animals generally, and more particularly when they are being transported from one place toanother or when they are used as performing animals or when they are kept in captivity or confinement
- To advise the Government or any local authority or other person on improvements in the design of vehicles soas to lessen the burden on draught animals
- To take all such steps as the Board may think fit for (amelioration of animals) by encouraging or providing for, the construction of sheds, water-troughs and the like and by providing for veterinary assistance to animals:
- To advise the Government or any local authority or other person in the design of slaughter-houses or themaintenance of slaughter houses
- To advise the Government regarding the slaughter of animals so that unnecessary pain or suffering,

whether physical or mental, is eliminated in the pre-slaughter stages as far as possible, and animals are killed; wherevernecessary, in as humane a manner as possible;

- To take all such steps as the Board may think fit to ensure that unwanted animals are destroyed by local authorities, whenever it is necessary to do so, either instantaneously or after being rendered insensible to painor suffering.
- To encourage by the grant of financial assistance or otherwise, the formation or establishment of pinjra poles, rescue homes, animal shelters, sanctuaries and where animals and birds may find a shelter when they have become old and useless or when they need protection:
- To co-operate with, and co-ordinate the work of, associations or bodies established for the purpose of preventing unnecessary pain or suffering to animals or for the protection of animals and birds;
- To give financial and other assistance to animal welfare organisations functioning in any local area or to encourage the formation of animal welfare organisations in any local area which shall work under the generalsupervision and guidance of the Board;
- To advise the Government on matters relating to the medical care and attention which may be provided in animal hospital, and to give financial and other assistance to animal hospitals whenever the Board thinks it necessary to do so;
- To impart education in relation to the humane treatment of animals and to encourage the formation of public opinion against the infliction of unnecessary pain or suffering to animals and for the promotion of animal welfare by means of lectures, books, posters, cinematographic exhibitions and the like;
- To advise the Government on any matter connected with animal welfare or the prevention of infliction ofunnecessary pain or suffering on animals.

CPCSEA GUIDELINES

- The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) is a statutory Committee, which is established under Chapter 4, Section 15(1) of the Prevention of Cruelty to Animals Act 1960

- India is one of the pioneering countries to institute Prevention of Cruelty to Animals Act in 1960 whereas suchAct was instituted in France in 1963 and in USA in 1966.

OBJECTIVES

The goal of these Guidelines is to **promote the humane care of animals used in biomedical and**

behavioral research and testing with the basic objective of **providing specifications that will enhance animal well-being**, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals

The main functions of CPCSEA are:

1. Registration of establishments conducting animal experimentation or breeding of animals for this purpose
2. Selection and assignment of nominees for the Institutional Animal Ethics Committees of the registered establishments
3. Approval of Animal House Facilities on the basis of reports of inspections conducted by CPCSEA
4. Permission for conducting experiments involving use of animals
5. Recommendation for import of animals for use in experiments
6. Action against establishments in case of established violation of any legal norm/stipulation
7. Conduct of Training Programmes for the Nominees of CPCSEA
8. Conduct / Support of Conference / workshop on Animal Ethics

Constitution

- 2 members each from ICMR, ICAR, CSIR nominated by the central govt.
- 2 members representing universities granting medical and veterinary degrees nominated by the central govt.
- 1 member of the Lok Sabha and 1 of the Rajya Sabha to be elected by the houses respectively
- 5 non- officials representing persons actively engaged in the promotion of animal welfare nominated by the central government

CORE MEMBERS

- Hon. Smt. Maneka Gandhi – drafted under chairperson, CPCSEA
- Mr. A.K.Joshi – Member Secretary, CPCSEA

Subcommittee members

- Dr. Manju Sharma – secretary, department of biotechnology
- Members
- Dr. Vasanth muthuswamy- Sr. DDG, Indian Council Of Medical Research
- Dr. Lal Krishna – ADG,(AH) ICAR, New Delhi
- Dr. S.S. Murugan – SGS India private limited, Chennai

Quarantine, stabilization and separation Quarantine-

- Separation of newly received animals from those already in the facility until the health and possibly themicrobial status of newly received animal have been determine.
- A minimum duration of quarantine for small animal-1 week and for larger animal-6 week (acclimatization)
- Physiologic, psychological and nutritional stabilization should be given before their use.
- Duration of stabilization will depend on type and duration of animal transportation, and species of animal.

Separation-

- Physical separation of animal by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioural changes due to interspecies conflict.
- Housing different species in separate room.
- It shall be acceptable to house different species in the same room only if they have a similar pathogen statusand are behaviourally compatible.

Surveillance, Diagnosis, Treatment and Control of disease

- All animal should be observed for signs of illness, injury, or abnormal behaviour by animal house staff.
- Animals that show signs of a contagious disease should be isolated from healthy animals in the colony.

Animal care and technical personnel

- Animal care require technical and husbandry support.
- Institution should employ people trained in laboratory animal or provide for both formal and on the job trainingto ensure effective implementation of the program.

Personal hygiene

- Animal care staff maintain a high standard of personal cleanliness.
- Clothing suitable for use in the animal facility should be supplied and laundered by the institution.
- It acceptable to use disposable gear such as gloves, masks, head covers, coats, coveralls and shoe covers.
- Person should change clothing as often as is necessary to maintain personal hygiene.
- Personnel should not be permitted to eat, drink, smoke or apply cosmetic in animal rooms.

Multiple surgical procedures on single animal

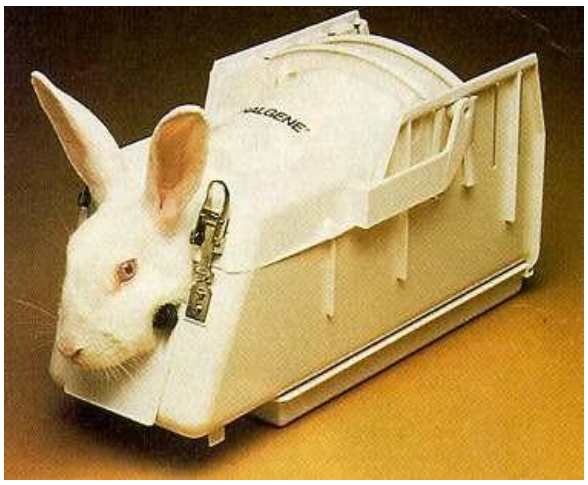
Multiple surgical procedures on a single animal for any testing or experiment are not to be practiced unless specified in aprotocol only approved by the IAEC.

Durations of experiments

No animal should be used for experimentation for more than 3 years unless adequate justification is provided.

Physical restraint

- Restraint devices cannot be used simply as a convenience in handling or managing animals.
- The period of restraint should be the minimum required to accomplish the research objectives.
- Provision should be made for observation of the animal at appropriate intervals



Physical relationship of animal facilities of laboratories

- Animal shall be housed in an isolated building located as far away from human habitations as possible and notexposed to dust, smoke, noise, wild rodent, insects and birds.
- This separation can be accomplished by having the animal quarters in a separate building, wing, floor or room.
- The animal room should occupy about 50-60% of the total constructed area and the remaining area should be utilized for service such as stores, washing, office and staff, machine rooms, quarantine and corridors.
- Since animals are very sensitive to environmental changes, sharp fluctuations in temperature, humidity, light,sound and ventilation should be avoided.

PHYSICAL FACILITIES

- **BUILDING MATERIALS**- moisture-proof, fire-resistant, seamless materials are most desirable

for interior surfacesincluding vermin and pest resistance.

- **CORRIDOR-** wide enough to facilitate the movement of personnel as well as equipments and should be keptclean.
- **UTILITIES-** water lines, drain pipes and electrical connection
- **ANIMAL ROOM DOORS-** rust, vermin and dust proof. it properly within their frames and provided with anobservation window.
- **FLOORS-** smooth, moisture proof, non-absorbent, skid-proof, resistant to wear, acid, solvents, adverse effects ofdetergents and disinfectants. Capable of supporting racks, equipment and stored items without becoming gouged, cracked, or pitted.
- **DRAINS-** floor drains are not essential in all rooms used exclusively for housing rodents.
- **WALLS & CEILINGS-** free of cracks, unsealed utility penetrations, or imperfect junction with doors, ceilings, floorsand corners.
- **STORAGE AREAS-** separate storage areas should be designed for feed, bedding, cages and materials not in use.
- **FACILITIES FOR SANITIZING EQUIPMET AND SUPPLIES-** an area for sanitizing cages and ancillary equipment isessential with adequate water supply.
- **EXPERIMENTAL AREA-** should be carried out in a separate area from the place where animals are housed.

ENVIRONMENT

TEMPERATURE AND HUMIDITY CONTROL-

- Air conditioning
- Temperature with in the range of 64.4-84 ^{o} f
- Relative humidity- 30-70% throughout the year
- For large animal comfortable zone-18-37˚c

POWER & LIGHTING-

- The electrical system should be safe and provide appropriate lighting and a sufficient no. Of power outlets.
- A time control light system should be used.

NOISE CONTROL- noise free environment

FOOD

- Should be fed palatable, non-contaminated and nutritionally adequate food.
- Feeders should allow easy access to food while avoiding contamination by urine and faeces.
- Food should be available in amounts sufficient to ensure normal growth in immature animals and maintenanceof normal body weight, reproduction and lactations in adults.
- Areas in which diets are stored should be kept clean and enclosed to prevent entry of insects or other animals. Diet should be free from heavy metals.

WATER

- Fresh
- Potable
- Uncontaminated

WATER DISPOSAL

The most preferred method of waste disposal is incineration. If wastes must be stored before removal , the waste storage area should be separated from other storage facilities and free of flies, cockroaches, rodents and other vermin.

PEST CONTROL

Programs designed to prevent, control, or eliminate the presence of or infestations by pests are essential in an animalenvironment

EMERGENCY, WEEKEND AND HOLIDAY CARE

Animal should be cared for by qualified personnel every day, including weekends and holidays, to safeguards their well-being including emergency veterinary care.

RECORD KEEPING

- Animal house plans
- Animal house staff record
- Health record of staff/animals
- All SOPs relevant to the animals
- Breeding, stock, purchase and sales records
- Minutes of institute animals ethics committee meetings
- Records of experiments conducted with the no. of animals used
- Death record
- Clinical record of sick animals training record of staff involved in animal activities
- Water analysis report

STANDARD OPERATING PROCEDURES (SOPS)/ GUIDELINES

Maintain SOPs describing procedures/ methods adapted with regard to animal husbandry, maintenance, breeding,animal house microbial analysis and experimentation record.

SOPs should contain following items-

- Name of author
- Title of SOP
- Date of preparation
- Reference of previous SOP on the same subject and date
- Location and distribution of SOPs with sign of each recipient
- Objectives
- Detailed information of the instruments used in relation with animals
- Normal value of all parameters.

TRANSPORT OF LABORATORY ANIMALS

The main considerations for transport of animals are the mode of transport, the containers, the animal density in cages,food and water during transit, protection from transit infection, injuries and stress.

ANAESTHESIA

- Sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment
- Before use actual anaesthetics the animals is prepared for anaesthesia by over night fasting and using pre-anaesthetics.
- Local or general anaesthetics may be used depending on type of surgical procedure.

DISPOSAL

The transgenic and knockout animal should be first euthanized and then disposed off as prescribed elsewhere inthe guidelines

A record of disposal and the manner of disposal should be kept as a matter of routine

A **knockout mouse** is a laboratory **mouse** in which researchers have inactivated, or "knocked out," an existinggene by replacing it or disrupting it with an artificial piece of DNA.

A **transgenic animal** is one whose genome has been changed to carry genes from other **species**. The nucleus of all cells in every living organism contains genes made up of DNA. These genes store information that regulates how our bodies form and function

Procedures to be followed

- When the experiments are performed by the institutions, their heads shall be responsible for fulfilling theobjectives of the act

- Where individuals run any experiment on animals, they shall be individually responsible for avoidance of cruelty
- The experiments should be performed while the animals are under the influence of an anesthetic and if therecovery of the animal involves serious suffering, it should be destroyed
- If possible use a small animal for an experiment and where possible replace animal with models, films, cell linesetc.
- The animals intended to be used for experiments should be properly cared for before and after experimentsand record of experiments performed should be maintained

Offences and penalties

- If any person contravens any conditions imposed by the committee, he may be punished with a fine extendingupto Rs. 200

Summary

1. The act was instituted in 1960 to prevent the infliction of unnecessary pain or suffering on animals and for thatpurpose to amend the law relating to the prevention of cruelty to animals
2. The act includes committees like the Animal Welfare Board of India and CPCSEA
3. **CPCSEA:** Committee for the Purpose of Control And Supervision of Experiments on Animals
4. Committee supervises experimentation on animals
5. Stipulates procedures to followed while carrying out experimentation on animals

DRUG PRICE CONTROL ORDER (DPCO)

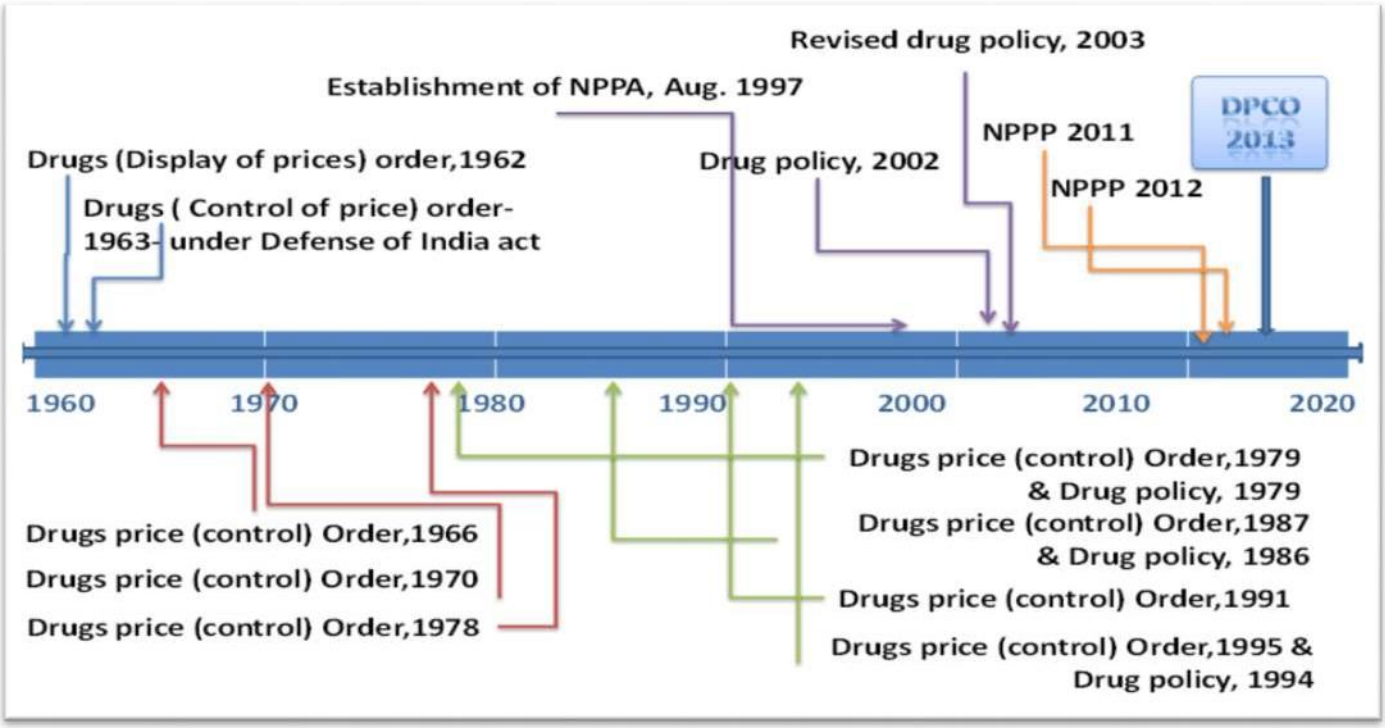
Contents of this chapter

- Introduction
- History of Price regulation in India
- Objectives and Definition

Learning Objectives

- At the end of this lecture, student will be able to
  - Define the terminologies of DPCO
  - Describe the history of Price regulation in India
  - Discuss the objectives of DPCO

History of Price regulation in India



Drug Price Control Order 1995

The drug price control order (DPCO) is an order issued by the government under the Essential Commodities Act, 1955 which enables it to fix the prices of some essential bulk drugs and their formulations.

The origin of this control dates back to 1970 when for the first time the government placed limits on profitabilityof pharmaceutical companies.

Why under Essential Commodities act????

- Since drugs are essential for the health of the society

Are all the drugs marketed under price control???

- Only 74 out of about 500 commonly used bulk drugs are kept under statutory price control

DPCO provides

- The list of price controlled drugs.
- **Procedures** for fixation of prices of drugs.
- Method of **implementation** of prices fixed by Government.
- Penalties for contravention of provisions

All formulations containing the bulk drugs either in a single or combination form fall under the price controlcategory.

Objectives

- ✓ To achieve adequate **production**
- ✓ To regulate equal distribution
- ✓ To maintain and increase supply of bulk drugs
- ✓ To make at **fair prices.**
- ✓ To ensure availability, at ***reasonable prices*** of essential and life-saving and prophylactic medicines of goodquality.
- ✓ Promoting the rational use of drugs in the country
- ✓ To encourage **cost-effective production** with economic sizes

National Pharmaceutical Pricing Authority (NPPA)

- Is an independent body of experts established on **29th August 1997** entrusted with

The task of fixation/ revision of prices of pharmaceutical products (bulk drugs and formulations)

Enforcement of provisions of the DPCO

Monitoring of the prices of controlled and decontrolled drugs in the country

DEFINITIONS

Bulk Drugs:-

It means any pharmaceutical, chemical and biological or plant product that conforms to Pharmacopoeial standardsspecified in D&Cact, 1940.

Ceiling Price:-

Price fixed by government for scheduled formulation.

A single maximum selling price that is applicable throughout the country

Drug:- Substance intended to be used for or in the diagnosis, treatment, or prevention of any disease or disorder inhuman or animal.

Retail price:-

Retail price of drug fixed in accordance with provisions of DPCO 1995 and include ceiling price.

Scheduled bulk drug:-

It means bulk drug specified in first schedule.

DPCO 2013

The DPCO 2013 empowers the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of 348essential drugs along with their specified strengths and dosages under NLEM 2011.

Main Features of the DPCO 2013 IMP

The new order will bring 348 drugs & their 652 formulations under price control.

The new policy uses a market-based pricing mechanism against the earlier proposed cost-plus method. The ceiling price would be calculated by taking the simple average of prices of all brands of a drug with a marketshare of 1% or more.

All strengths and dosages specified in the NLEM (National list of Essential Medicines) will be under price control

Margins of wholesalers & retailers have been cut down to 8% & 16% respectively.

Companies selling medicines above the government-mandated ceiling rated would have to slash prices tomeet the demands of new rules, but those selling drugs below the ceiling price wouldn't be allowed to raiseprices.

Firms that launch new medicines can sell them at or below government-set price caps.

Existing firms will not be allowed to stop production of any drug without permission from the government.

Drug producers will be permitted an annual increase in the retail price in sync with the wholesale price index.

Which drugs will come under price control?

- This order doesn't cover **patented** drugs. Earlier in March this year the Department of pharmaceuticals (DOP)had issued a draft proposal on price negotiation of patented drugs.
- Prices of 652 formulations spanning over 27 therapeutic classes are regulated by DPCO 2013.
- Prices of some additional anti-cancer drugs including the much talked about Imatinib, Carboplatin, Dacarbazine, Daunorubicn, Chlorambucil, Oxaliplatin and some anti-retroviral cocktails like

Zidovudine-Lamivudine- Nevirapine and Stavudine- Lamivudine will now be regulated by the current order.

- However in certain emergency case, the patents can be broken down and the drugs can be released into themarket.

Prices of Bulk Drugs

- Government has power to fix the maximum sale price.

While fixing the sale price government shall take into following considerations:-

- Post-tax return of 14% on net worth.
- Return of 22% on capital employed.
- On the basic stage of production, post tax return of 18% on net worth or 26% on capital employed
- At the time of production of drug, manufacturer fill detail in form-1 and give necessary information togovernment within 15 days.
- Make necessary inquiry and then government fix maximum sale price if bulk drug and noted in official gazette.
- Govt. also fix or revise the price of non-scheduled bulk drugs.

Information Required from Manufacturer to Government

For the both scheduled and non-scheduled bulk drugs

List of drug produced with cost in form 1 and 2 resp.

But for scheduled bulk drugs it should given by 30 september every year.

RETAIL PRICE OF FORMULATION – DPCO 1995

FORMULA FOR CALCULATION OF RETAIL PRICE:

.P. = (M.C.+C.C.+P.M.+P.C.)X(1+ MAPE / 100) + ED.

WHERE, R.P. = RETAIL PRICE

M.C.= MATERIAL COST

C.C.= CONVERSION COST

P.M.= PACKAGING MATERIAL COST

P.C.= PACKING CHARGES

ED = EXCISE DUTY (Taxes)

MAPE= MAXIMUM ALLOWABLE POST MANUFACTURING EXPENSES

How Prices are Calculated & Fixed – DPCO 2013

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shallbe calculated as under:

Step1: First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2: Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

DPCO 2013

Margin to retailer: While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percentof price to retailer as a margin to retailer shall be allowed.

Maximum retail price:

(1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling pricenotified by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Ceiling price + Local Taxes as applicable

(2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined bythe Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Retail Price + Local Taxes as applicable

What's new in this DPCO?

New Pricing methodology: Earlier method used manufacturing costs as a basis to calculate ceiling prices

This DPCO 2013 excludes bulk drugs from price alterations but formulation prices will fall

What this means: API/Bulk Drug Manufacturing, which has seen declining trend for the past many years now will havean upsurge (hopefully)

DPCO 2013 promotes R&D by excluding new drug, new process or NDDS from DPCO for 5 years

Power to Fix Retail Price of Scheduled Formulation

- Government fix the retail price of bulk drug.

- Manufacturer use drugs in scheduled formulation.
- For price revision of such formulation manufacturer should apply within 30 days.
- From date of receipt of complete information govt. Fix retail price within 2 months.

• Without approval of government,

• Manufacturer should not increase retail price of drug.

• Manufacturer should not marketed new formulation.

• No person shall sell imported scheduled formulation.

Power to Fix Ceiling Price of Scheduled Formulation

- Government fix the ceiling price of scheduled formulation.
- Ceiling price for formulation including those sold under generic name.
- Fixed revised ceiling price for schedule formulation either on it's own motion or on application made inprescribed form.

Power to Revise Price of Bulk Drug and Formulation

- Government fix or revise retail price of one or more formulation.
- As the pre-tax return on sales turnover of formulation then the scheduled and non-scheduled formulation.

Fixation of Price Under Certain Circumstances

- If any manufacturer of bulk drug fails to submit the application for fixation or revision of price or fails to giveinformation within specified time period.
- Then government fix price of the bulk drug.

Power to Recover Overcharged Amount

- If any manufacturer or importer charging higher price than the price fixed by government
- Then government may recover the overcharged amount.

Control of Sale Prices of Bulk Drug and Formulation

- No person or retailer shall sale the drug/ formulation
- To any customer at increasing price specified in current price list indicated on container label.

Sale of Split Quantity of Formulation

- No dealer shall sell the loose quantity of formulation
- At price exceeding pro-rata prices of formulation plus 5%.

Schedules Related to DPCO act, 1995

FIRST SCHEDULE

- First Schedule includes 76 bulk drugs.
- Eg. Penicillin, ranitidine, chloroquine etc

SECOND SCHEDULE

- Different forms included :-
- Form- 1:- application for fixation/ revision of price.
- Form- 2:- information related with price of non-scheduled bulk drug.
- Form-3:- application for approval/revision of price of scheduled formulation.
- Form-4:- application for approval/revision of price of scheduled formulation imported in finished form.
- Form-5 :- form of price list
- Form- 6:- yearly information on turnover and allocation of sales and expenses.

THIRD SCHEDULE

- Category A :- Large unit with turnover exceeding rs. 6 crores per annum.
- Category B :- Medium sized unit turnover between rs. 1 crore to 6 crore per annum.
- Category C :- Other units with turnover of less than rs. 1 crore per annum.

OFFENCES AND PENALTIES

Penalties—

- Shall be punishable with imprisonment *for one year and also liable* to fine.
- In the case of any other order, with **imprisonment for not less than three months** but which may extend toseven years and also be liable to fine.

What companies do to avoid getting into DPCO

- Changing the composition of the formulation by putting in ingredients (if possible) that are not subject to pricecontrol.
- Transferring the brand to a small–scale unit, which produces the product for a subsidiary.

Case studies:

- Pfizer for instance did change the composition of its B–complex vitamin brand *Becousules* (which ranks secondin branded sales in the country). However the DPCO clamped down on this move and brought the entire rangeof B–complex vitamins under its purview.

Summary

- Bulk drug means any pharmaceutical, chemical and biological or plant product conform to

Pharmacopoeialstandards specified in d & c act, 1940.

- Ceiling Price is Price fixed by government for scheduled formulation
- Drug is a Substance intended to be used for or in the diagnosis, treatment, or prevention of any disease ordisorder in human or animal
- To achieve adequate production, regulate equal distribution, maintain and increase supply of bulk drugs andmake at fair prices

Question Bank

Long essays (10 marks):

1. What are CPCSEA guidelines for breeding and stocking of animals?
2. Write about transport and acquisition of animals for experiment.
3. Write a note on power to suspend or revoke of registration as per Prevention of Cruelty to animals Act.
4. Describe the facilities to be maintained for experimentation on animals under CPCSEA guidelines.
5. Define magic remedies. Write the classes of advertisements prohibited under D&MR Act.
6. Define drugs, advertisements and magic remedies as per D&MR Act.
7. Discuss the classes of advertisements exempted conditionally under D&MR Act.
8. Define magic remedies. Give the classes of advertisements.

Short essays (5 marks):

1. Write a short note on National List of Essential Medicines (NLEM).
2. Explain Drugs Price Control Order (DPCO).
3. Write a note on retail price and ceiling price of scheduled formulations.
4. Write a short on DPCO.
5. Write a short on sale price of bulk drugs and retail price of formulations.
6. Who maximum allowable post manufacturing expenses (MAPE) is calculated as per DPCO
7. Give the constitution and functions of Institutional Animal Ethical Committee (IAEC).
8. Write the objectives and prevention of cruelty to animals. What are the parts of CPCSEA guidelines?
9. Write the offences and penalties in contravention of D&MR Act.
10. Define advertisement and mention the objectives of D&MR Act.
11. Define magic remedies. Write a note on scrutiny of misguiding advertisements related to drugs.
12. Write about salient features of D&MR Act.