

Unit- 4

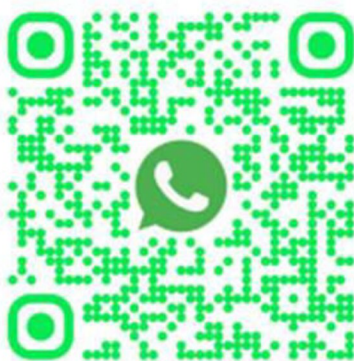
Pharmaceutical Jurisprudence

B.Pharma 5th Sem Notes

Unit: 4

- **Drugs & Magic Remedies Act – 1954:** Objectives, Definitions, Prohibition of Advertisements, Exempted Advertisements, Offences & Penalties
- **Prevention of Cruelty to Animals Act – 1960:** Objectives, Definitions, IAEC, CPCSEA Guidelines – Breeding/Stocking, Experiments, Transfer/Acquisition, Records, Suspension of Registration, Offences & Penalties
- **NPPA & DPCO-2013:** Objectives, Definitions, Sale Price of Bulk Drugs, Retail Price of Formulations, Ceiling Price of Scheduled Formulations, NLEM

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DRUGS & MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT – 1954

DRUGS & MAGIC REMEDIES ACT – 1954

Introduction & Background

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (Act No. 21 of 1954) was enacted to control and prohibit misleading and false advertisements of drugs and magic remedies. It came into force on 1st April, 1955. The Act was enacted in response to the widespread misuse of advertising by unscrupulous persons who made false and exaggerated claims about drugs and 'magical' preparations. The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 were framed under this Act. The Act extends to the whole of India.

Objectives of Drugs & Magic Remedies Act – 1954

OBJECTIVES

- To control and prohibit misleading advertisements relating to drugs
- To prohibit advertisements of remedies claiming magical or miraculous properties
- To prevent false claims about drugs that may be prejudicial to public health
- To prohibit advertisements of drugs claimed to be useful for diagnosis, cure, mitigation, treatment or prevention of diseases listed in the Schedule
- To protect the public from unscrupulous advertisers who exploit patients by making false therapeutic claims
- To prevent exploitation of patients suffering from serious diseases like cancer, tuberculosis, diabetes, mental disorders, etc.
- To regulate print, visual, and other media from carrying objectionable drug advertisements

Important Definitions

Term	Definition
Advertisement	Any notice, circular, label, wrapper, document, hoarding, or any announcement made by word of mouth, or produced or transmitted

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	by sound in any manner or by visual representation including any publication in newspaper
Drug	Has the same meaning as assigned to it in the Drugs & Cosmetics Act, 1940; includes Ayurvedic, Siddha, Unani, Homeopathic medicines
Magic Remedy	Includes talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease or disorder
Prescribed	Prescribed by rules made under this Act
Schedule	The Schedule appended to the Act listing diseases/conditions for which advertisements are prohibited
False Advertisement	An advertisement which is false or misleading in a material particular relating to a drug
Manufacturer	Any person who manufactures or processes drugs as defined under Drugs & Cosmetics Act, 1940

Prohibition of Certain Advertisements

◆ A. Section 3 – Prohibition of Advertisements of Magic Remedies

No person shall take any part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

SECTION 3 – PROHIBITED ADVERTISEMENTS OF MAGIC REMEDIES

- The procurement of miscarriage in women or prevention of conception in women
- The maintenance or improvement of the capacity of human beings for sexual pleasure
- The correction of menstrual disorder in women
- The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the Act
- Any advertisement which claims or implies that any drug is a magical remedy (talisman, mantra, kavacha, etc.) capable of treating or curing any disease

◆ B. Section 4 – Prohibition of Misleading Advertisements

Section 4 prohibits any advertisement relating to a drug if the advertisement:

SECTION 4 – PROHIBITED MISLEADING ADVERTISEMENTS

- Directly or indirectly gives false impression regarding the true character of the drug
- Makes false claim for the drug
- Is otherwise false or misleading in any material particular
- Claims that the drug is useful for diagnosis, cure, mitigation, treatment or prevention of diseases mentioned in the Schedule
- Uses false testimonials or endorsements of medical practitioners that are fabricated
- Makes exaggerated claims about safety or efficacy of the drug without scientific evidence

◆ C. Diseases Listed in the SCHEDULE (for which advertisements are prohibited)

The Schedule to the Act lists diseases and conditions for which drug advertisements claiming to diagnose, cure, mitigate, treat, or prevent are prohibited:

Category	Diseases/Conditions Listed in Schedule
Infectious Diseases	Appendicitis, Arteriosclerosis, Bladder disease, Bright's disease, Cancer, Cataract, Deafness, Dropsy, Epilepsy or fits, Fevers in general, Glaucoma
Hormonal/Metabolic	Diabetes, Goitre, Obesity, Leucorrhoea, Menstrual disorders
Mental/Neurological	Insanity (mental disorder), Paralysis, Locomotor ataxia, Hysteria
Reproductive Health	Disorders of the prostate gland, Sexual impotence, Sterility in women, Miscarriage/abortion
Cardiovascular	Blood pressure, Heart disease, Rheumatic heart disease
Others	Smallpox, Plague, Sexually transmitted diseases (e.g. Gonorrhoea, Syphilis), Leprosy, Tuberculosis (TB)

Classes of Exempted Advertisements

The following classes of advertisements are exempt from the provisions of the Act:

EXEMPTED ADVERTISEMENTS [Section 14]

1. Advertisements appearing in any publication intended solely for the use of medical, dental, veterinary, nursing, midwifery or pharmaceutical professions (e.g., medical journals, drug information bulletins)
2. Advertisements sent only to registered medical practitioners, hospitals, clinics, pharmacists – i.e., professional communications

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3. Advertisements of drugs approved for use in treatment of recognized diseases where the advertisement is in conformity with the approved label
4. Advertisements made by the Central or State Government for public health purposes
5. Advertisements of drugs included in the Schedule to the Drugs and Cosmetics Act if the advertisement is consistent with the approved labelling
6. Any sign-board or notice exhibited at a pharmacy or place of business of a registered pharmacist giving information regarding drugs supplied at that place (price list, stock information)
7. Advertisements of drugs sent to medical practitioners as samples or promotional material (detailing) – under defined conditions

Offences & Penalties

Offence [Section]	Penalty
Publication of objectionable advertisement – first offence [Sec 7]	Imprisonment up to 6 months, OR Fine, OR Both
Publication of objectionable advertisement – subsequent offence [Sec 7]	Imprisonment up to 1 year, OR Fine, OR Both
Importing into India any document containing prohibited advertisement [Sec 8]	Same as Section 7 above (up to 6 months first offence; 1 year subsequent)
Taking part in publication (editor, printer, publisher)	All persons involved in publication are liable; editor is deemed to have published unless proved otherwise
Advertising a drug as magic remedy/talisman/mantra without scientific basis	Prosecution under Section 7
Making a false/misleading advertisement and continuing after notice of prohibition	Enhanced fine + imprisonment in subsequent offences

IMPORTANT NOTES – DMR ACT 1954

- Cognizance: No court shall take cognizance of an offence under this Act except on a complaint made by a government officer authorized by the Central/State Government
- Editor's Responsibility: Unless proved otherwise, the editor of a newspaper/publication shall be deemed to have published an objectionable advertisement
- Power to Seize: Authorities can seize and confiscate documents/material containing objectionable advertisements

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- • Application: Covers print media, outdoor advertising (hoardings), electronic media (added by amendments)

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PREVENTION OF CRUELTY TO ANIMALS ACT – 1960 & CPCSEA GUIDELINES

PREVENTION OF CRUELTY TO ANIMALS ACT – 1960

Introduction & Background

The Prevention of Cruelty to Animals Act, 1960 (Act No. 59 of 1960) was enacted to prevent infliction of unnecessary pain or suffering on animals. It came into force on 26th December, 1960. Chapter IV of the Act specifically deals with experiments on animals and is of particular relevance to pharmaceutical sciences. The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) was established under Section 15 of this Act to regulate animal experimentation in India.

Objectives of the Prevention of Cruelty to Animals Act – 1960

OBJECTIVES

- To prevent the infliction of unnecessary pain, suffering, or cruelty to animals
- To establish the Animal Welfare Board of India (AWBI) to promote animal welfare
- To regulate and control experiments performed on animals for scientific purposes
- To set up a statutory committee (CPCSEA) to supervise and control animal experimentation
 - To ensure that animal experiments are performed only when absolutely necessary and with minimum suffering
 - To enforce the 3R principles – Replacement, Reduction, and Refinement in animal experimentation
 - To prescribe procedures for registration of establishments performing animal experiments
 - To penalize acts of cruelty toward animals including scientific cruelty

Definitions

Term	Definition
Animal	Any living creature other than a human being; includes birds, reptiles, and aquatic creatures
Experiment	Any experiment on an animal performed for the purpose of any research or for the purpose of obtaining new information, testing a substance or product, or for educational demonstration
Experimenter	Any person who performs or is responsible for an experiment on animals

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Registered Institution	An establishment registered with CPCSEA for the purpose of performing experiments on animals
Cruelty	Causing unnecessary pain or suffering to an animal; includes beating, overloading, neglecting, torturing, or killing an animal in an unnecessarily cruel manner
Prescribed	Prescribed by rules made under this Act
Animal Welfare Board	The Animal Welfare Board of India constituted under Section 4 of the Act
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals – constituted under Section 15
IAEC	Institutional Animal Ethics Committee – constituted at each registered institution as per CPCSEA guidelines

Institutional Animal Ethics Committee (IAEC)

◆ A. Constitution of IAEC

Every institution registered with CPCSEA is required to constitute an Institutional Animal Ethics Committee (IAEC). The IAEC is responsible for monitoring animal experiments at the institutional level.

CONSTITUTION OF IAEC

- Biological Scientist: 2 scientists with experience in the use of animals in research (from the institution)
- Veterinarian: 1 veterinarian registered with the Veterinary Council of India, preferably with experience in laboratory animal medicine
- Scientist from CPCSEA Nominee: 1 scientist nominated by CPCSEA as its representative
- Scientist in charge of Animal House: 1 scientist in charge of the institutional animal house facility
- Sociologist / Scientist from different biological discipline: 1 member from outside the institution who is concerned with animal welfare
- Occupational Health Expert: Recommended to have a member responsible for occupational health of personnel
- Chairperson: One member is designated as Chairperson (usually a senior scientist)
- Quorum: Minimum 4 members must be present for any IAEC meeting to be valid
- Tenure: 3 years; eligible for re-nomination

◆ B. Functions of IAEC

FUNCTIONS OF IAEC

- Review and approve all animal experiment proposals before commencement

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- Ensure that the 3Rs (Replacement, Reduction, Refinement) principles are applied in all experiments
- Monitor ongoing animal experiments for compliance with approved protocols
- Inspect animal house facilities periodically to ensure proper standards of care and housing
- Maintain records of all animal experiments performed at the institution
- Submit annual reports of animal use to CPCSEA
- Investigate complaints of cruelty or violations of CPCSEA guidelines
- Recommend measures for improvement of animal welfare at the institutional level
- Ensure that all personnel handling animals are adequately trained

CPCSEA – Constitution & Functions

◆ A. Constitution of CPCSEA

Membership	Details
Chairperson	A person of eminence in the field of animal welfare / zoology / veterinary science – appointed by Central Government
Members (ex-officio)	Representatives from Ministry of Health, Ministry of Agriculture, Ministry of Education, ICMR, CSIR, ICAR
Nominees of Central Govt.	Persons with experience in medicine, pharmaceutical sciences, biology, animal welfare
NGO Representatives	Representatives of recognized animal welfare organizations
Veterinary Experts	Veterinary scientists with expertise in laboratory animal science
Total Membership	As prescribed by the Central Government; typically 10–15 members
Term	3 years; eligible for re-appointment

◆ B. Functions of CPCSEA

FUNCTIONS OF CPCSEA

- Supervise and control experiments on animals performed in India
- Grant registration to institutions wishing to perform animal experiments
- Prescribe standards for housing, feeding, care and handling of laboratory animals
- Nominate CPCSEA representatives to all IAECs of registered institutions
- Inspect and monitor registered institutions to ensure compliance with guidelines
- Prescribe and update CPCSEA Guidelines on Breeding & Stocking, Experiments, etc.
- Take action against institutions violating guidelines – including suspension/revocation of registration
- Advise the Central Government on matters relating to animal experiments
- Promote use of alternatives to animal testing wherever possible (3R principles)

CPCSEA Guidelines – Breeding and Stocking of Animals

CPCSEA has prescribed detailed guidelines for the breeding and stocking of laboratory animals to minimize suffering and ensure quality.

BREEDING & STOCKING GUIDELINES

- Breeding Facility: Must be separate from experimentation area; must have CPCSEA approval
- Animal Suppliers: Animals for experimentation must be obtained only from CPCSEA-registered breeding establishments
- Housing Standards: Adequate space per animal as specified (cage dimensions for mice, rats, rabbits, guinea pigs, dogs, monkeys, etc.)
- Temperature: 20–26°C for most rodents; specific ranges for each species
- Humidity: 40–70% relative humidity; controlled ventilation with 12–15 air changes per hour
- Light Cycles: 12 hours light : 12 hours dark cycle; light intensity 200–300 lux at cage level
- Bedding: Autoclaved or heat-treated; changed regularly; suitable for each species
- Food & Water: Pelleted/standard diet specific to species; ad libitum (free access) water from approved sources
- Health Monitoring: Regular health surveillance; genetic monitoring for inbred strains; pathogen-free status maintained
- Stocking Density: Prescribed number of animals per cage to prevent overcrowding and fighting
- Record Keeping for Breeding: Species, strain, number, source, date of birth, parents, litter details – all recorded

CPCSEA Guidelines – Performance of Experiments

GUIDELINES FOR PERFORMING EXPERIMENTS

- Protocol Approval: ALL experiments must be approved by IAEC before commencement; no retrospective approval
- Minimum Animals: Use the minimum number of animals necessary to obtain statistically valid results
- Species Selection: Use species lowest on phylogenetic scale that is scientifically appropriate; prefer invertebrates/cell cultures where possible (3R-Replacement)
- Anesthesia & Analgesia: Appropriate anesthesia must be used for all painful procedures; pain relief (analgesia) must be provided post-procedure
- Surgical Procedures: All surgery must be performed under aseptic conditions with appropriate anesthetics by trained personnel

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- Multiple Survival Surgeries: Not permitted on the same animal except where scientifically justified and approved by IAEC
- Euthanasia: Must use humane methods prescribed by CPCSEA (e.g., CO₂ inhalation, barbiturate overdose, cervical dislocation for rodents)
- Paralytic Agents: Neuromuscular blocking agents (like curare) cannot be used in the absence of anesthesia
- Post-procedure Care: Animals must receive adequate veterinary care and monitoring after procedures
- Endpoints: Defined endpoints to minimize suffering; avoid death-as-endpoint studies where alternatives exist

Transfer and Acquisition of Animals for Experiments

Aspect	Details
Source of Animals	Animals for experiments must be obtained only from CPCSEA-registered breeding/supplier establishments
Import of Animals	Import of live animals or animal products for experiments requires prior permission from CPCSEA/DGFT; import permit mandatory
Transfer Between Institutions	Animals can be transferred between CPCSEA-registered institutions with proper documentation; health certificates required
Wild Animals	Experiments on wild-caught animals require special permission from CPCSEA + Wildlife Authorities; strongly discouraged
Protected Species	Experiments on animals listed under Wildlife Protection Act 1972 require special clearance
Acquisition Records	Date, species, strain, number, source, health status, and purpose must be recorded at time of acquisition
Transport Conditions	Animals must be transported in species-appropriate containers; access to food/water; temperature maintained; minimize travel time
Quarantine	Newly acquired animals must be quarantined for prescribed period before use in experiments (usually 1–2 weeks for rodents)

Records to be Maintained

MANDATORY RECORDS UNDER CPCSEA

- Animal Acquisition Register: Species, strain, source, number acquired, date, health status, purpose
- Experiment Register: Protocol number, IAEC approval date, experimenter name, species used, number of animals, experiment dates

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- Animal House Register: Daily census of animals (species-wise); births, deaths, transfers recorded daily
- Morbidity/Mortality Register: All cases of illness, unexpected death, cause of death documented
- Drug/Substance Administration Record: Substance, dose, route, frequency for each animal per experiment
- Veterinary Treatment Records: All treatments given to animals – drug, dose, date, veterinarian signature
- Personnel Training Records: Names and qualifications of all staff; evidence of training in laboratory animal care
- Annual Returns: Submitted to CPCSEA; species-wise number of animals used; type of experiments; outcomes
- Retention Period: Records must be retained for at least 5 years; available for inspection by CPCSEA officers

Power to Suspend or Revoke Registration

CPCSEA has the authority under the PCA Act and its rules to suspend or revoke the registration of an institution if it fails to comply with the prescribed guidelines.

Ground for Action	Action Taken
Non-compliance with CPCSEA guidelines (housing, care, experiment protocol)	Show-cause notice; Inspection; Suspension of registration for specified period
Performing experiments without IAEC approval	Immediate suspension pending inquiry; possible revocation
Failure to maintain mandatory records	Warning; Suspension; Possible revocation
Failure to submit annual returns to CPCSEA	Warning notice; Suspension of new experiment approvals
Cruelty to laboratory animals beyond experimental necessity	Revocation of registration; Criminal prosecution under PCA Act
Failure to constitute or maintain IAEC	Suspension of registration until IAEC reconstituted
Import of animals without proper permission	Seizure of animals; Penalty; Possible registration suspension
Repeated violations after restoration of registration	Permanent revocation of registration

Procedure for suspension/revocation: CPCSEA issues a show-cause notice giving the institution an opportunity to be heard; after considering the response, CPCSEA may

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suspend (for a specified period) or permanently revoke registration. The order of revocation can be appealed to the Central Government.

Offences & Penalties:

Offence [Section]	Penalty
Performing experiment on animal without registration [Sec 26]	Fine up to Rs. 200; Subsequent: Rs. 500 fine + possible imprisonment up to 3 months
Cruelty to animal during experiment (unnecessary suffering) [Sec 11]	Fine Rs. 10–50 (first offence); Rs. 25–100 (subsequent) or Imprisonment up to 3 months or Both
Using paralytic drugs without anesthesia	Fine; Suspension of registration by CPCSEA
Failing to maintain records as prescribed	Fine and/or suspension of registration
Performing experiment without IAEC approval	Suspension of registration; Show-cause notice; Fine
Importing animals without permission	Seizure; Penalty; Criminal prosecution
Registered institution allowing unregistered experimenter to conduct experiments	Fine; Suspension of registration

3R PRINCIPLES - (CPCSEA)

- **REPLACEMENT:** Replacing animal experiments with alternatives wherever scientifically and practically possible (e.g., cell cultures, computer models, in-vitro methods)
- **REDUCTION:** Using the minimum number of animals necessary to obtain scientifically valid data (statistical power analysis to determine sample size)
- **REFINEMENT:** Modifying procedures to minimize pain, suffering, distress, and improve animal welfare while achieving scientific objectives (better analgesia, humane endpoints, improved housing)

NPPA & DRUGS PRICE CONTROL ORDER (DPCO) – 2013

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) & DPCO – 2013

National Pharmaceutical Pricing Authority (NPPA)

◆ A. Introduction

The National Pharmaceutical Pricing Authority (NPPA) was established by the Government of India on 29th August, 1997 under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. It is an independent regulatory body that fixes and revises the prices of controlled bulk drugs and formulations in India. NPPA implements the Drug Price Control Order (DPCO) framed under the Essential Commodities Act, 1955.

◆ B. Objectives of NPPA

OBJECTIVES OF NPPA

- To fix and revise the prices of bulk drugs and formulations listed under price control
- To implement and enforce the provisions of the DPCO
- To ensure the availability of essential drugs at reasonable prices to the common people
- To monitor the prices of controlled and decontrolled drugs
- To deal with all legal matters related to drug pricing
- To maintain data on production, exports, imports, market share, and profitability of pharmaceutical manufacturers
- To prevent overpricing and exploitation of patients by pharmaceutical companies
- To advise the government on drug pricing policies and drug import/export

◆ C. Functions of NPPA

Function	Details
Price Fixation	Fix the prices of scheduled (controlled) bulk drugs and formulations; issue price notifications
Price Revision	Revise prices annually based on Wholesale Price Index (WPI) as per DPCO formula

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Monitoring	Monitor prices of all pharmaceuticals – both controlled and uncontrolled; report violations
Enforcement	Take action against manufacturers selling drugs above the notified ceiling price
Legal Matters	Handle court cases related to drug pricing; recover overcharges from manufacturers
Data Collection	Maintain MIS (Management Information System) database on all pharmaceuticals
Imports	Recommend import duties/concessions to balance domestic prices
Advisory	Advise Department of Pharmaceuticals on inclusion/exclusion from NLEM/DPCO schedules

Drugs Price Control Order (DPCO) – 2013

◆ A. Introduction

The Drugs Price Control Order, 2013 (DPCO-2013) was issued by the Government of India under Section 3 of the Essential Commodities Act, 1955. It came into force on 15th May, 2013, replacing DPCO-1995. The important feature of DPCO-2013 is that it uses a market-based pricing mechanism (unlike the cost-based pricing of DPCO-1995) to fix ceiling prices of formulations based on the simple average price of all brands having market share $\geq 1\%$ for a formulation listed under the National List of Essential Medicines (NLEM).

Important Definitions [Paragraph 2 of DPCO-2013]

Term	Definition
Bulk Drug (API)	Any pharmaceutical, chemical, biological, or plant product conforming to pharmacopoeial or other standards and which is used as active pharmaceutical ingredient (API) in the manufacture of formulations
Ceiling Price	The maximum price at which a scheduled formulation can be sold to the ultimate consumer, including all taxes
Formulation	A medicine in finished dosage form (tablet, capsule, syrup, injection, etc.) containing one or more bulk drugs with or without excipients, which is ready for administration to patients
Market-based Pricing	Ceiling price is calculated from the weighted average price of top-selling brands (market share $\geq 1\%$)
NLEM	National List of Essential Medicines – list of essential medicines notified by the Ministry of Health & Family Welfare

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Non-Scheduled Formulation	Formulations NOT listed in Schedule I of DPCO; prices are not controlled but monitored
Overpricing	Selling a drug at a price higher than the notified ceiling price – an offence under DPCO
Retail Price	Price at which formulation is sold to the consumer (MRP) inclusive of all taxes
Scheduled Formulation	Formulation listed in Schedule I of DPCO-2013 (medicines in NLEM) – subject to price control
Trade Margin	Difference between the price at which the manufacturer sells and the retail price – regulated under DPCO
Wholesale Price Index (WPI)	Index used for annual revision of ceiling prices; published by Ministry of Commerce

Sale Price of Bulk Drugs

The ceiling price for bulk drugs is set by NPPA. The following provisions apply to the sale price of bulk drugs:

SALE PRICE OF BULK DRUGS –PROVISIONS

- NPPA fixes the price of scheduled bulk drugs (APIs) under DPCO-2013
- Manufacturers cannot sell scheduled bulk drugs above the price fixed by NPPA
- The sale price is inclusive of all taxes and duties
- Import parity pricing: For imported bulk drugs, price is determined based on import parity (CIF value + customs duty + other charges)
- Annual revision: Prices of bulk drugs are revised annually based on changes in Wholesale Price Index (WPI)
 - The manufacturer must display the maximum sale price on the label of bulk drug containers
 - No bulk drug covered under DPCO can be sold at a price higher than the ceiling price fixed by NPPA
 - NPPA can grant exemptions from price control in specific circumstances (e.g., new drugs under patent)

Retail Price of Formulations:

The retail price (MRP) of formulations is determined as follows:

Aspect	Details
For Scheduled Formulations (NLEM)	Ceiling price is fixed by NPPA using market-based pricing formula; MRP cannot exceed ceiling price

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For Non-Scheduled Formulations	No ceiling price; manufacturer can fix MRP; NPPA monitors prices; price increase >10% per year not permitted without prior intimation to NPPA
Retail Price Formula (Scheduled)	Ceiling Price = [Sum of prices of all brands with $\geq 1\%$ market share] / Number of such brands + Applicable Taxes
MRP Labeling	MRP (inclusive of all taxes) must be printed on every pack; 'MRP inclusive of all taxes' to be stated
Trade Margins	DPCO does not directly fix trade margins; however, it expects manufacturer-to-retailer and retailer-to-consumer margins to be reasonable
Price on Label	Must show: MRP, batch no., mfg date, expiry date, manufacturer name & address
Import of Formulations	Import price is determined based on CIF value + applicable duties; not to exceed ceiling price for scheduled formulations

Retail Price & Ceiling Price of Scheduled Formulations

◆ A. Market-Based Pricing Formula (DPCO-2013)

CEILING PRICE CALCULATION FORMULA

- **Step 1:** Identify all brands of the scheduled formulation available in the market
- **Step 2:** Determine the market share of each brand (from IMS/IQVIA or equivalent market data)
- **Step 3:** Include all brands with market share $\geq 1\%$ (i.e., with significant market presence)
- **Step 4:** Calculate the Simple Average Price of these shortlisted brands
- Formula: Ceiling Price per unit = (Sum of prices of all shortlisted brands) / (Number of shortlisted brands)
- **Step 5:** Add applicable taxes (GST) to arrive at Maximum Retail Price (MRP)
- **Step 6:** NPPA notifies this ceiling price in the Official Gazette
- Annual Revision: Every year, ceiling prices are revised upward by the change in WPI
- Formula for Annual Revision: New Ceiling Price = Old Ceiling Price $\times (1 + \% \text{ change in WPI}/100)$

◆ B. Differences: Scheduled vs Non-Scheduled Formulations

Feature	Scheduled Formulations vs Non-Scheduled Formulations
Definition	SCHEDULED: Listed in Schedule I of DPCO-2013 (= medicines in NLEM) NON-SCHEDULED: Not listed in Schedule I

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Price Control	SCHEDULED: Ceiling price fixed by NPPA (price control) NON-SCHEDULED: No ceiling price; free pricing by manufacturer
Price Revision	SCHEDULED: Annual revision by WPI formula NON-SCHEDULED: Can increase by max 10%/year without prior intimation; > 10% needs NPPA notice
Examples	SCHEDULED: Paracetamol, Metformin, Amoxicillin, Atenolol, Aspirin NON-SCHEDULED: Branded combinations not in NLEM
MRP Compliance	SCHEDULED: Cannot sell above ceiling price; violation = overpricing offence NON-SCHEDULED: Must print MRP; cannot sell above printed MRP

National List of Essential Medicines (NLEM)

◆ A. Introduction

The National List of Essential Medicines (NLEM) is a list of essential medicines selected by the Government of India based on disease burden, safety, efficacy, and cost-effectiveness. The concept of essential medicines was introduced by WHO in 1977. In India, the Ministry of Health and Family Welfare (MoHFW) notifies the NLEM. The latest version is NLEM-2022. Medicines listed in NLEM are included in Schedule I of DPCO-2013 and are subject to price control.

◆ B. Objectives of NLEM

OBJECTIVES OF NLEM

- To identify and list drugs that satisfy the priority healthcare needs of the majority of the Indian population
- To facilitate rational use of drugs by healthcare providers
- To ensure availability and affordability of essential medicines to all sections of society
- To provide a basis for price control (through DPCO) ensuring access to essential medicines at reasonable prices
- To guide procurement policies of government health programs
- To serve as a basis for medicine supply in public health facilities (PHCs, CHCs, District Hospitals)
- To update the list periodically based on new evidence of efficacy, safety, and changing disease patterns

◆ C. Criteria for Inclusion in NLEM

CRITERIA FOR INCLUSION IN NLEM

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- **Relevance:** The medicine must address priority disease conditions in India (disease burden)
- **Efficacy & Safety:** Evidence-based efficacy and an acceptable safety profile (established clinical use)
- **Quality:** The medicine must conform to pharmacopoeial or equivalent quality standards
- **Cost-effectiveness:** Lowest possible cost for achieving therapeutic objective
- **Preference for Single-Ingredient Formulations:** Combination products included only where evidence strongly supports superiority
- **Availability:** Medicine should be available in adequate quantities in India
- **Not Patent-Protected (preferred):** Generic availability preferred to ensure affordability

◆ D. Categories of NLEM-2022 Medicines (Examples)

Category	Examples of Medicines	Use
Analgesics/Antipyretics	Paracetamol, Ibuprofen, Morphine	Pain relief, fever
Antibiotics	Amoxicillin, Azithromycin, Ciprofloxacin, Doxycycline	Bacterial infections
Antidiabetics	Metformin, Glibenclamide, Insulin (human)	Diabetes mellitus
Antihypertensives	Atenolol, Amlodipine, Enalapril, Losartan	Hypertension
Cardiovascular	Aspirin, Atorvastatin, Digoxin, Heparin	Heart disease, clotting
Antituberculosis	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	Tuberculosis
Antimalaria	Chloroquine, Primaquine, Artemether+Lumefantrine	Malaria
Gastrointestinal	Omeprazole, Metoclopramide, ORS, Zinc sulfate	GI disorders
Psychotropic	Haloperidol, Diazepam, Amitriptyline	Mental health
Vitamins/Minerals	Folic Acid, Iron, Vitamin B12, Calcium	Nutritional deficiencies
Vaccines	BCG, DPT, Polio, Hepatitis B, MMR	Immunization

◆ E. NLEM vs DPCO Relationship

Aspect	NLEM vs DPCO Relationship
NLEM	Published by Ministry of Health & Family Welfare; lists essential medicines; updated periodically (current: NLEM-2022)

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DPCO Schedule I	Contains ALL medicines from NLEM; these medicines are under price control
Mechanism	When a medicine is included in NLEM → it automatically comes under price control (DPCO Schedule I) → NPPA fixes ceiling price
Purpose	NLEM = rational medicine policy tool; DPCO = price control implementation tool; Together = affordable essential medicines
Updates	When NLEM is updated, DPCO Schedule I is also updated accordingly

EXAM-ORIENTED MCQs – PHARMACEUTICAL JURISPRUDENCE UNIT- 4

Q1. The Drugs and Magic Remedies (Objectionable Advertisements) Act was enacted in:

- a) 1940 b) 1948 c) 1954 d) 1960

✓ **Answer: c) 1954**

Q2. Which of the following is a 'Magic Remedy' under DMR Act 1954?

- a) Registered tablet b) Talisman or mantra claiming curative powers c) Ayurvedic decoction d) Homeopathic globule

✓ **Answer: b) Talisman or mantra claiming curative powers**

Q3. Under DMR Act 1954, which advertisements are EXEMPTED from the prohibition?

- a) Advertisements in newspapers b) Advertisements on TV c) Advertisements in medical journals for healthcare professionals d) Hoarding advertisements

✓ **Answer: c) Advertisements in medical journals for healthcare professionals**

Q4. The penalty for the first offence under DMR Act 1954 is:

- a) 3 months imprisonment b) 6 months imprisonment c) 1 year imprisonment d) Rs. 500 fine only

✓ **Answer: b) 6 months imprisonment**

Q5. CPCSEA stands for:

- a) Central Pharmaceutical Committee for Safe and Effective Animals b) Committee for Purpose of Control and Supervision of Experiments on Animals c) Central Prevention Committee for Safety of Experimental Animals d) None of above

✓ **Answer: b) Committee for Purpose of Control and Supervision of Experiments on Animals**

Q6. The 3R principles in animal experimentation stand for:

- a) Record, Report, Register b) Replacement, Reduction, Refinement c) Review, Regulate, Report d) Restrict, Reduce, Remove

✓ **Answer: b) Replacement, Reduction, Refinement**

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Q7. IAEC (Institutional Animal Ethics Committee) must have at minimum how many members present for a valid meeting?

- a) 2 b) 3 c) 4 d) 5

✓ **Answer: c) 4**

Q8. Under CPCSEA guidelines, which animal is preferred for experiments when scientifically appropriate?

- a) Monkey b) Dog c) Species lowest on phylogenetic scale d) Rabbit

✓ **Answer: c) Species lowest on phylogenetic scale**

Q9. NPPA was established in the year:

- a) 1990 b) 1995 c) 1997 d) 2013

✓ **Answer: c) 1997**

Q10. DPCO-2013 replaced which earlier order?

- a) DPCO-1979 b) DPCO-1987 c) DPCO-1995 d) DPCO-2002

✓ **Answer: c) DPCO-1995**

Q11. Under DPCO-2013, the ceiling price of a scheduled formulation is calculated based on:

- a) Cost of production + profit b) Simple average price of brands with $\geq 1\%$ market share c) Weighted average of all brands d) Government-fixed price tables

✓ **Answer: b) Simple average price of brands with $\geq 1\%$ market share**

Q12. Prices of scheduled formulations are revised annually based on:

- a) Consumer Price Index (CPI) b) Wholesale Price Index (WPI) c) GDP growth rate d) Import parity price

✓ **Answer: b) Wholesale Price Index (WPI)**

Q13. Medicines in NLEM are included in which Schedule of DPCO-2013?

- a) Schedule A b) Schedule H c) Schedule I d) Schedule II

✓ **Answer: c) Schedule I**

Q14. The maximum price increase allowed for NON-scheduled formulations per year without prior NPPA notice is:

- a) 5% b) 10% c) 15% d) 20%

✓ **Answer: b) 10%**

Q15. Which Act empowers the Government to issue the Drug Price Control Order (DPCO)?

- a) Drugs & Cosmetics Act 1940 b) Pharmacy Act 1948 c) Essential Commodities Act 1955 d) NDPS Act 1985

✓ **Answer: c) Essential Commodities Act 1955**

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