BP606T · B.Pharm Semester VI · Theory Notes

Pharmaceutical Jurisprudence

Unit IV — DMR Act, PCA Act & DPCO

Unit IV (7 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit IV (7 hours).

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(Unit IV — Part A)

3.1 Learning Objectives

After studying this chapter, you will be able to:

1 State the objectives and definitions of the Drugs and Magic Remedies Act.

2 Explain the prohibition of certain advertisements.

3 List the classes of exempted advertisements.

4 State the offences and penalties under the Act.

5 State the objectives and definitions of the Prevention of Cruelty to Animals Act, 1960.

6 Describe the Institutional Animal Ethics Committee (IAEC).

7 Explain the CCSEA guidelines for breeding, stocking, experiments, transfer/acquisition of animals and records.

8 Explain the power to suspend or revoke registration.

9 State the offences and penalties.

3.2 Definitions and Terminology

Term	Simple meaning
Objectionable advertisement	An ad that falsely claims a drug/magic remedy can cure certain diseases or conditions, or misleads the public.
Magic remedy	A talisman, mantra, charm or any "magical" object claimed to cure disease — covered by the Act so quacks cannot advertise miracles.
Prohibition	A legal ban — here, on publishing certain advertisements.
Exempted advertisement	An ad that is *allowed* even though it relates to the listed diseases (classes specified in the rules).
Cruelty (to animals)	Causing unnecessary pain or suffering to an animal.
IAEC (Institutional Animal Ethics Committee)	The committee in each research institution that approves and monitors animal experiments.
CCSEA	Committee for Control and Supervision of Experiments on Animals — the national body supervising animal experiments (named in the syllabus as CCSEA).
Registration (of animal facilities)	Animal houses/labs must be registered with the supervisory committee to conduct experiments.
Suspend / revoke registration	Temporarily stop (suspend) or cancel (revoke) the permission of a facility that violates the rules.

INFOGRAPHIC CONCEPT — "Two Shields": Draw two shields side by side. Shield 1 = **"Protects PEOPLE from false ads"** (Drugs & Magic Remedies Act — stops miracle-cure advertisements). Shield 2 = **"Protects ANIMALS from cruelty"** (PCA Act — IAEC + CCSEA guard every lab animal). A pharmacist stands between the shields: honest promotion on one side, humane research on the other.

3.3 Explanation — Part A: Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

3.3.1 Why the Act exists — simple story first

Technical concept: This Act bans advertisements that falsely claim cures for certain diseases or promote "magic remedies".

Simple explanation: Imagine a newspaper ad saying "Guaranteed cure for diabetes in 7 days with our magic locket!" Sick people may waste money and skip real treatment. This Act makes such advertisements illegal.

Example: An ad claiming a herbal powder "cures cancer" cannot be legally published. An ad for a registered medicine giving factual information within the rules is different.

Key takeaway: The Act = ban on misleading "miracle cure" advertisements for drugs and magic remedies.

3.3.2 Objectives

1 To **prohibit** advertisements of drugs that claim to cure/treat certain diseases and conditions specified in the Act.

2 To **prohibit** advertisements of "magic remedies" claiming miraculous powers.

3 To **protect the public** from being misled into wasting money or delaying proper treatment.

4 To prescribe **offences and penalties** for violations.

3.3.3 Definitions (core)

- **Drug:** As defined in the Act (substances used for diagnosis, treatment, mitigation or prevention of disease).
- **Magic remedy:** Includes talismans, mantras, charms and similar objects claimed to have miraculous powers for curing disease.
- **Advertisement:** Any notice, circular, label, wrapper or announcement made orally, in writing, or by any means to promote a drug or magic remedy.

3.3.4 Prohibition of certain advertisements

Simple points:

1 No person shall publish an advertisement claiming that a drug can **cure, treat or prevent** any of the diseases/conditions listed in the Act's schedule.

2 No person shall advertise a **magic remedy** with claims of miraculous curative powers.

3 The prohibition covers all media — print, broadcast, wall paintings, pamphlets, and electronic media.

CAUTION: The exact list of diseases/conditions is given in the schedule to the Act (as amended from time to time). Do not memorise or quote a list from memory — write "the diseases and conditions specified in the schedule to the Act".

3.3.5 Classes of exempted advertisements

Simple explanation: Some advertisements are *allowed* even in this strict law. The rules specify exempted classes — broadly:

Exempted class (type)	Simple meaning
Advertisements to **medical professionals**	Scientific information sent to doctors/pharmacists (not the general public)
Advertisements in **scientific/medical journals**	Technical literature for professionals
Advertisements as **permitted by the rules**	Classes specifically exempted in the rules/notifications

Key takeaway: The law targets *public-facing* miracle claims, not genuine scientific communication to professionals.

3.3.6 Offences and penalties

Offence	Penalty (type)
Publishing a prohibited advertisement (first offence)	Punishment as prescribed (imprisonment and/or fine)
Repeat offence	Enhanced punishment as prescribed

CAUTION: Write "punishable with imprisonment and/or fine as prescribed under the Act" — confirm current figures from the official text.

3.4 Explanation — Part B: Prevention of Cruelty to Animals Act, 1960

3.4.1 Why the Act exists — simple story first

Technical concept: This Act prevents unnecessary pain and suffering to animals, including in research.

Simple explanation: Pharmacy students test new drugs on animals (rats, mice, rabbits). The law says: you may use animals for genuine research, but you must minimise their suffering, follow approved procedures, and get permission from an ethics committee. Cruelty without justification is punishable.

Example: Before testing a new tablet on rats, the college's IAEC must approve the experiment plan; the animal house must be registered; records must be kept.

Key takeaway: PCA Act = animals may be used for real science, but only humanely, with permission and records.

3.4.2 Objectives

1 To **prevent infliction of unnecessary pain or suffering** on animals.

2 To regulate **experiments on animals** for scientific purposes.

3 To provide for the **registration of animal facilities** and supervision through committees.

4 To prescribe **offences and penalties** for cruelty.

3.4.3 Definitions (core)

- **Animal:** Any living creature other than a human being (as defined in the Act).
- **Cruelty:** Doing any act that causes unnecessary pain or suffering to an animal.
- **Experiment:** A procedure on a living animal for scientific purposes.

3.4.4 Institutional Animal Ethics Committee (IAEC)

Simple explanation: Every institution that does animal experiments must have its own ethics committee — a group that reviews each proposed experiment and asks: "Is this experiment necessary? Can fewer animals be used? Will pain be minimised?"

Typical composition and role (broad pattern):

- Includes scientists of the institution, a veterinarian, and outside/nominee members as per guidelines;
- **Approves, modifies or rejects** proposed animal experiments;
- **Monitors** ongoing experiments and the animal house;
- Ensures compliance with CCSEA guidelines.

Analogy: IAEC is like the "principal's permission slip" for animal work — no slip, no experiment.

3.4.5 CCSEA guidelines

Simple explanation: CCSEA (Committee for Control and Supervision of Experiments on Animals) is the national watchdog. It issues guidelines covering:

1 **Breeding and stocking of animals:** Animal houses must maintain proper housing, feeding, hygiene, ventilation and veterinary care; only healthy, suitable animals are bred/stocked.

2 **Performance of experiments:** Experiments only for genuine scientific purpose; use the minimum number of animals; minimise pain (anaesthesia/analgesia where needed); trained personnel only.

3 **Transfer and acquisition of animals for experiment:** Animals must be obtained from registered/recognised sources; transfer between institutions follows the prescribed procedure and records.

4 **Records:** Every facility must maintain records — number of animals acquired, used, experiments performed, and disposal — open to inspection.

CAUTION: Detailed guideline requirements change with notifications — write "as per the latest CCSEA guidelines/notifications".

3.4.6 Power to suspend or revoke registration

- Facilities conducting animal experiments must be **registered**.
- If a facility violates the Act or guidelines, the authority may **suspend** (temporarily stop) or **revoke** (cancel) its registration after due procedure (opportunity to explain).
- Without valid registration, experiments cannot be conducted.

3.4.7 Offences and penalties

Offence	Penalty (type)
Treating animals cruelly (unnecessary pain/suffering)	Punishment as prescribed (fine and/or imprisonment)
Conducting experiments without registration / against guidelines	Punishment as prescribed

CAUTION: Confirm exact penalties from the latest official text; write "as prescribed under the Act".

3.5 Pharmacy Relevance (India context)

- Pharmacists in **marketing** must ensure promotional material never makes prohibited miracle-cure claims.
- Pharmacists in **R&D and colleges** work with IAEC approvals for preclinical animal studies.
- Retail pharmacists should not stock or promote products advertised with prohibited claims.

3.6 Key Points

1 DMR Act, 1954 bans advertisements claiming cures for scheduled diseases and ads of "magic remedies".

2 Exemptions: professional/scientific communication and classes exempted in the rules.

3 Violations punishable with imprisonment and/or fine as prescribed.

4 PCA Act, 1960 prevents unnecessary pain/suffering to animals.

5 IAEC approves and monitors animal experiments in each institution.

6 CCSEA guidelines cover breeding/stocking, conduct of experiments, transfer/acquisition, and records.

7 Registration of facilities can be suspended or revoked for violations.

8 Cruelty and unregistered experiments are offences.

3.7 Common Confusions

- **DMR Act vs Drugs and Cosmetics Act:** DMR controls *advertisements*; D&C controls *manufacture and sale*.
- **Exempted ads:** Scientific ads to doctors are allowed; public miracle-cure ads are banned.
- **IAEC vs CCSEA:** IAEC = institution-level committee; CCSEA = national supervisory committee.

3.8 Common Mistakes

- Listing specific diseases from memory for the DMR schedule — always write "diseases specified in the schedule to the Act".
- Saying animal experiments are fully banned — they are *regulated*, not banned.
- Quoting fine amounts from memory.

3.9 Mnemonics

- **DMR — "P-E-O": P**rohibit miracle ads, **E**xempt professional ads, **O**ffences punishable.
- **Animal research — "A-B-T-R-S": A**pproval (IAEC), **B**reeding standards, **T**ransfer rules, **R**ecords, **S**uspend/revoke for violations.

3.10 Exam Summary

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 prohibits advertisements claiming cures for the diseases specified in its schedule and advertisements of magic remedies, while exempting professional/scientific communications and other classes in the rules; violations are punishable. The Prevention of Cruelty to Animals Act, 1960 prevents unnecessary suffering to animals; animal experiments need IAEC approval, registered facilities, and compliance with CCSEA guidelines on breeding, stocking, conduct of experiments, transfer/acquisition and records; registration can be suspended or revoked, and cruelty is punishable.

3.11 One-Minute Revision

- DMR 1954: no miracle-cure ads to public; professional ads exempt; offence punishable.
- PCA 1960: no unnecessary suffering; IAEC approves experiments; CCSEA guidelines (breeding, experiments, transfer, records); registration can be suspended/revoked.

3.12 Exam Questions

Short answers:

1 What is a "magic remedy" under the DMR Act?

2 Name the classes of exempted advertisements.

3 What is the role of IAEC?

4 On what grounds can registration of an animal facility be suspended?

Long answers:

1 Discuss the salient features of the Drugs and Magic Remedies (Objectionable Advertisements) Act with reference to prohibited and exempted advertisements.

2 Describe the provisions of the Prevention of Cruelty to Animals Act, 1960 relating to animal experiments, IAEC and CCSEA guidelines.

MCQs:

1 The DMR Act prohibits: a) All drug ads b) Ads claiming cures for scheduled diseases and magic remedies c) Doctor prescriptions d) Price labels

2 Advertisements in medical journals to doctors are: a) Prohibited b) Exempted c) Taxed d) Ignored

3 IAEC is constituted at the: a) National level b) Institutional level c) District level d) WHO level

4 CCSEA guidelines cover: a) Only breeding b) Breeding, experiments, transfer and records c) Only pricing d) Only imports

5 Registration of an animal facility can be: a) Never cancelled b) Suspended or revoked for violations c) Sold d) Transferred freely

Viva:

1 Can a company advertise "cures diabetes in 7 days"? Why not?

2 Who approves your college's rat experiment?

3 What records must an animal house keep?

Application-based:

1 A newspaper carries an ad for a "magic ring that cures blood pressure". Advise the advertiser on legal risk.

2 A new pharma college wants to start animal testing. List the legal steps.

3.13 References

- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (bare Act, latest official text).
- The Prevention of Cruelty to Animals Act, 1960 (bare Act, latest official text).
- CCSEA guidelines/notifications (latest official text).

(Unit IV — Part B)

4.1 Learning Objectives

After studying this chapter, you will be able to:

1 State the objectives of the National Pharmaceutical Pricing Authority (NPPA).

2 State the objectives and definitions of the Drugs Price Control Order (DPCO), 2013.

3 Explain the sale prices of bulk drugs.

4 Explain the retail price of formulations.

5 Explain the retail price and ceiling price of scheduled formulations.

6 Describe the National List of Essential Medicines (NLEM).

4.2 Definitions and Terminology

Term	Simple meaning
NPPA	National Pharmaceutical Pricing Authority — the government body that fixes and monitors medicine prices in India.
DPCO, 2013	Drugs (Prices Control) Order, 2013 — the legal order under which drug prices are controlled.
Bulk drug	The active pharmaceutical ingredient (API) — the raw "medicine chemical" before it becomes a tablet/syrup.
Formulation	The finished medicine (tablet, capsule, syrup, injection) made from bulk drug(s) plus excipients.
Scheduled formulation	A formulation whose bulk drug is in the NLEM schedule — its price is directly controlled (ceiling price).
Ceiling price	The maximum price at which a scheduled formulation may be sold — fixed by NPPA.
Retail price	The price at which the medicine is sold to the patient/customer (printed as MRP).
NLEM	National List of Essential Medicines — the official list of medicines considered essential for public health in India.
MRP	Maximum Retail Price — printed on the pack; the shop cannot charge more.

INFOGRAPHIC CONCEPT — "The Price-Control Pipeline": Draw a pipeline with 4 tanks. Tank 1 = **NLEM** (government lists essential medicines). Tank 2 = **Schedule** (formulations of those medicines become "scheduled"). Tank 3 = **NPPA fixes ceiling price** (maximum allowed price calculated by formula). Tank 4 = **MRP on the pack** (retailer cannot exceed it). A valve between tanks = **DPCO 2013**, the law that makes the flow happen. Non-scheduled formulations: price monitored, annual increase limited as per the order.

4.3 Explanation

4.3.1 Why price control exists — simple story first

Technical concept: Essential medicines must remain affordable to all citizens.

Simple explanation: If there were no control, a life-saving medicine could be priced so high that poor patients die for lack of money. The Government therefore fixes maximum prices for essential medicines through NPPA under DPCO 2013.

Example: A commonly used essential antibiotic tablet has a ceiling price fixed by NPPA; every brand's MRP for that strength must stay at or below the ceiling.

Key takeaway: Price control = Government fixes maximum prices of essential medicines so treatment stays affordable.

4.3.2 NPPA — objectives

1. **To fix and revise prices** of scheduled (controlled) drugs and formulations.
2. **To monitor prices** of all medicines, including non-scheduled ones.
3. **To ensure availability** of medicines at reasonable prices.
4. **To take action** against overcharging (charging above the ceiling price) — including recovery of overcharged amounts with interest as per the order.
5. **To advise the Government** on drug pricing policy.

4.3.3 DPCO, 2013 — objectives

1. To **regulate the prices** of bulk drugs and formulations in India.
2. To fix **ceiling prices** for scheduled formulations (NLEM-based).
3. To regulate **retail prices** of formulations.
4. To ensure **availability** of essential medicines at fair prices.
5. To provide for **recovery of overcharged amounts** and penalties for violations.

4.3.4 Definitions (core, in simple words)

- **Bulk drug:** the active ingredient (API).
- **Formulation:** finished dosage form containing bulk drug(s).
- **Scheduled drug/formulation:** one included in the schedule to the order (linked to NLEM).
- **Ceiling price:** maximum price fixed for a scheduled formulation.
- **Retail price:** price to the consumer, inclusive of taxes, printed on the label.

CAUTION: Exact legal wordings are in the DPCO text — paraphrase in simple words in exams and add "as defined in the DPCO, 2013".

4.3.5 Sale prices of bulk drugs

Simple explanation: The price at which the API manufacturer sells the bulk drug to formulation makers can be regulated under the order so that the final medicine price stays reasonable.

Key points:

- Bulk drug prices are **monitored** and may be fixed/controlled as per the order's provisions.
- Manufacturers must **furnish price information** to NPPA as required.
- The idea: control the input (API) cost so the output (tablet) price stays fair.

4.3.6 Retail price of formulations

Simple explanation: The retail price is the MRP printed on the pack — the maximum the chemist can charge the patient.

Key points:

1. Every manufacturer fixes the retail price as per the formula/procedure in the order.
2. For **scheduled formulations**, the retail price cannot exceed the **ceiling price** fixed by NPPA.
3. For **non-scheduled formulations**, manufacturers fix prices themselves, but annual increases are limited as per the order, and NPPA monitors them.
4. The retail price must be **printed on the label**; charging above it is an offence under the order.

4.3.7 Retail price and ceiling price of scheduled formulations

Point	Simple meaning
Scheduled formulation	Formulation of a bulk drug listed in the schedule (NLEM-based)
Ceiling price	Maximum price fixed by NPPA using the prescribed formula (based on market data of brands)
Retail price vs ceiling price	Retail price (MRP) of every brand must be **ceiling price**
Revision	NPPA revises ceiling prices as per the order (e.g., annual revision linked to wholesale price index, as provided)
New drug	Special provisions exist for pricing of new drugs (as per the order)

Flowchart — how a ceiling price reaches the patient:

```
NLEM lists essential medicines
  ↓
Schedule to DPCO includes their formulations
  ↓
NPPA calculates & notifies ceiling price
  ↓
Manufacturer prints MRP ≤ ceiling price
  ↓
Retailer sells at ≤ MRP  →  patient pays fair price
```

CAUTION: The exact calculation formula and revision mechanism are prescribed in the DPCO and NPPA notifications — describe the *concept* in exams and add "as per the latest DPCO provisions/notifications".

4.3.8 National List of Essential Medicines (NLEM)

Simple explanation: NLEM is the Government's official list of medicines that every Indian should be able to get — the most important, safe, effective and cost-effective drugs for the country's health needs.

Key points:

1. Prepared by experts and **revised periodically** (new editions add/remove medicines).
2. Forms the **basis of the DPCO schedule** — price control starts from this list.
3. Guides **public procurement** (government hospitals buy NLEM medicines) and rational prescribing.
4. Includes medicines across categories — e.g., antibiotics, analgesics, cardiovascular drugs, vaccines (illustrative; confirm current list from the latest NLEM edition).

Analogy: NLEM is like the "essential grocery list" for the nation's medicine cupboard — the items the country must never run short of, at prices people can afford.

4.4 Pharmacy Relevance (India context)

- Retail pharmacists must sell scheduled formulations **at or below MRP** — overcharging is punishable.
- Hospital pharmacists prefer NLEM medicines for procurement (cost-effective, price-controlled).
- Industry pharmacists in regulatory affairs file price-related intimations to NPPA.

4.5 Key Points

1. NPPA fixes/monitors medicine prices; DPCO 2013 is the legal instrument.
2. Bulk drug = API; formulation = finished medicine.
3. Scheduled formulations (NLEM-based) have a **ceiling price** fixed by NPPA.
4. Retail price (MRP) must be printed and cannot exceed the ceiling price for scheduled items.
5. Non-scheduled formulations: self-priced, monitored, annual increase limited.
6. Overcharging is recoverable with consequences under the order.
7. NLEM = official essential-medicines list; basis of price control and public procurement.

4.6 Common Confusions

- **Ceiling price vs MRP:** Ceiling price = Government's maximum for the formulation; MRP = brand's printed price, which must be ceiling price.
- **Scheduled vs non-scheduled:** Scheduled = price directly fixed; non-scheduled = monitored with limited annual hikes.

- **NPPA vs DPCO:** NPPA = the *authority*; DPCO = the *legal order* it works under.

4.7 Common Mistakes

- Saying NPPA fixes prices of *all* medicines — it directly fixes *scheduled* ones and monitors the rest.
- Quoting a ceiling-price formula or WPI percentage from memory — write "as per the prescribed formula in the latest DPCO/notifications".

4.8 Mnemonics

- **Price pipeline — "N-S-C-R": N**LEM **S**chedule **C**eiling price **R**etail (MRP).
- **NPPA jobs — "F-M-A": F**ix prices, **M**onitor prices, **A**ct against overcharging.

4.9 Exam Summary

The National Pharmaceutical Pricing Authority implements the Drugs (Prices Control) Order, 2013: it fixes ceiling prices for scheduled formulations (based on the NLEM-linked schedule), regulates retail prices, monitors bulk-drug and non-scheduled formulation prices, and acts against overcharging. The retail price printed on the pack cannot exceed the ceiling price for scheduled formulations. The National List of Essential Medicines is the periodically revised official list of essential drugs that forms the basis of price control and public procurement.

4.10 One-Minute Revision

- NPPA + DPCO 2013 = medicine price control in India.
- Bulk drug (API) formulation (finished medicine).
- Scheduled (NLEM) ceiling price by NPPA MRP ceiling.
- Non-scheduled self-priced, monitored, limited annual increase.
- NLEM = essential medicines list; basis of schedule + procurement.

4.11 Exam Questions

Short answers:

1 What are the objectives of NPPA?

2 Define: bulk drug, formulation, scheduled formulation, ceiling price.

3 What is NLEM and why is it important?

4 Distinguish between ceiling price and retail price.

Long answers:

1 Discuss the salient features of DPCO, 2013 with reference to ceiling price and retail price of scheduled formulations.

2 Write notes on: (a) NPPA, (b) NLEM.

MCQs:

1 NPPA works under: a) Pharmacy Act b) DPCO, 2013 c) NDPS Act d) MTP Act

2 Ceiling price is fixed for: a) All formulations b) Scheduled formulations c) Only imports d) Only vaccines

3 MRP of a scheduled formulation must be: a) Above ceiling price b) Equal to cost c) At or below ceiling price d) Decided by retailer

4 NLEM is: a) A price list b) The official list of essential medicines c) A company directory d) A tax schedule

5 Bulk drug means: a) Finished tablet b) Active pharmaceutical ingredient c) Excipient d) Packing material

Viva:

1 Who fixes the ceiling price of a scheduled tablet?

2 Can a chemist charge above MRP?

3 What happens if a company overcharges?

Application-based:

1 A new brand of an NLEM antibiotic is launched. Explain the pricing steps before it reaches the chemist.

2 A patient complains of being charged above MRP. What is the legal position?

4.12 References

- The Drugs (Prices Control) Order, 2013 (latest official text/notifications).
- National List of Essential Medicines (latest edition, Government of India).
- NPPA notifications (latest official text).