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PHARMACEUTICAL JURISPRUDENCE

UNIT 4

TOPIC :

- **National Pharmaceutical Pricing Authority :** Drugs Price Control Order (DPCO) Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

National Pharmaceutical Pricing Authority (NPPA) and Drugs (Prices Control) Order, 2013 (DPCO 2013)

- The National Pharmaceutical Pricing Authority (NPPA) is an independent body under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.
  It was established in 1997 to fix, revise, and regulate the prices of pharmaceutical drugs in India and to ensure availability of essential medicines at affordable prices to all citizens.
- The NPPA enforces the provisions of the Drugs (Prices Control) Order (DPCO) — the latest version being DPCO 2013 — issued under the Essential Commodities Act, 1955.

Objectives of NPPA and DPCO 2013

Main Objectives	Explanation
1. Price Regulation	To fix and control the prices of essential drugs and ensure affordability.
2. Fair Distribution	To ensure continuous availability of essential medicines across India.
3. Prevention of Profiteering	To prevent manufacturers and retailers from charging excessive prices.
4. Encourage Domestic Production	To promote production of essential drugs within India.
5. Implementation of NLEM	To regulate the prices of drugs listed under the National List of Essential Medicines (NLEM).
6. Transparency	To ensure fair and transparent pricing policy for both consumers and manufacturers.
7. Monitoring and Enforcement	To monitor drug prices and take legal action against violations.

Important Definitions (as per DPCO, 2013)

Term	Definition
Bulk Drug (Active Pharmaceutical Ingredient)	Any substance used directly or as a component in manufacturing a drug that provides its therapeutic value.
Formulation	A medicine prepared from one or more bulk drugs with excipients in a specific dosage form (tablet, capsule, injection, etc.).
Scheduled Formulation	A formulation containing any bulk drug listed in the First Schedule of DPCO (i.e., drugs included in NLEM).
Ceiling Price	The maximum price (excluding local taxes) that a manufacturer can charge for a scheduled formulation.
Retail Price	The final price at which a drug is sold to the consumer, including all margins and taxes.
Manufacturer	Any person who manufactures or imports a drug for sale or distribution.
Wholesaler / Retailer	Persons involved in the supply and sale chain of the drug to the consumer.

Sale Prices of Bulk Drugs

Under DPCO 2013, the NPPA is empowered to:

- Fix or revise the ceiling price of bulk drugs listed in the schedule.
- Determine the average price of all major brands having ≥1% market share.
- Monitor non-scheduled drugs to ensure their prices do not increase beyond a prescribed limit.

Pricing Formula for Bulk Drugs

The ceiling price is fixed based on the simple average of prices of all brands with at least 1% market share in the previous year.

Formula:

$$Ceiling\ Price\ (P_c) = (Average\ Price\ of\ Brands\ with\ \geq 1\%\ Market\ Share) + Local\ Taxes$$

Retail Price of Formulations

A. Scheduled Formulations

- Retail price of scheduled drugs is based on the ceiling price fixed by NPPA.
- No manufacturer can sell above this price (excluding taxes).
- Retailers and wholesalers can add only a limited margin as per government norms.

B. Non-Scheduled Formulations

- Prices are not directly controlled, but the annual price increase is limited to 10% per year as per WPI (Wholesale Price Index).
- NPPA monitors these prices to prevent overcharging.

Retail Price & Ceiling Price of Scheduled Formulations

A. Ceiling Price

- It is the maximum permissible price that manufacturers can charge for any scheduled formulation.
- NPPA calculates ceiling prices for each drug included in NLEM (National List of Essential Medicines).
- All manufacturers must sell below or equal to the ceiling price.

Formula for Scheduled Formulations:

$$Ceiling\ Price\ (P_c) = \left(\frac{\sum_{i=1}^{n}(P_i \times M_i)}{\sum_{i=1}^{n} M_i}\right)(1 + WPI)$$

Where:

- Pi = Price of brand i per unit
- Mi = Market share of brand i
- WPI = Wholesale Price Index adjustment (annual revision)

B. Revision of Prices

- NPPA revises ceiling prices annually based on WPI inflation.
- Manufacturers must reduce prices immediately when NPPA announces a lower ceiling.
- Non-compliance may result in recovery of overcharged amounts with interest.

National List of Essential Medicines (NLEM)

The National List of Essential Medicines (NLEM) is a list of medicines that are considered essential to meet the healthcare needs of the majority of the population. These drugs are selected based on their efficacy, safety, cost-effectiveness, and public health relevance.
The list helps in ensuring availability, accessibility, and affordability of quality medicines at all levels of the healthcare system.

Objectives of NLEM

The main objectives of the NLEM are:

1. To promote rational use of medicines and prevent misuse or overuse.
2. To ensure availability of essential drugs at all public health facilities.
3. To guide the procurement, supply, and prescription of medicines in both government and private sectors.
4. To facilitate the implementation of Drug Price Control Orders (DPCO) for price regulation of essential medicines.
5. To promote equitable access to medicines for all socio-economic groups.
6. To provide a framework for pharmaceutical policy and health programs of the government.

Criteria for Selection of Medicines in NLEM

Medicines are included in NLEM based on the following criteria:

- They satisfy the priority healthcare needs of the population.
- They have proven efficacy, safety, and quality.
- They are cost-effective compared to other available alternatives.
- They are available in sufficient quantity and appropriate dosage forms.
- They are recommended for diseases that are prevalent in India.
- They have stable shelf-life and easy storage conditions suitable for Indian climate.

Classification of Medicines in NLEM

NLEM classifies medicines under broad therapeutic categories, such as:

1. Antimicrobial agents (e.g., amoxicillin, ciprofloxacin)
2. Anticancer drugs (e.g., methotrexate, tamoxifen)
3. Cardiovascular drugs (e.g., atenolol, amlodipine)
4. Analgesics and antipyretics (e.g., paracetamol, ibuprofen)
5. Antidiabetic drugs (e.g., metformin, glimepiride)
6. Vitamins and minerals (e.g., folic acid, vitamin D)
7. Vaccines (e.g., BCG, DPT, MMR)
8. Anesthetics and sedatives (e.g., lignocaine, diazepam)
9. Hormones (e.g., insulin, thyroxine)
10. Gastrointestinal drugs (e.g., omeprazole, ranitidine)

Implementation of NLEM under DPCO 2013

- NLEM forms the basis for identifying drugs whose prices will be controlled under the Drugs (Prices Control) Order, 2013.
- Ceiling prices are fixed for all medicines included in NLEM.
- Manufacturers cannot sell essential medicines above the ceiling price fixed by the National Pharmaceutical Pricing Authority (NPPA).
- Prices are revised annually based on the Wholesale Price Index (WPI).

Updates and Revisions

- The first NLEM was published in 1996, followed by updates in 2003, 2011, 2015, and 2022.
- The NLEM 2022 includes 384 medicines covering 27 therapeutic categories.
- Revisions are made periodically based on disease patterns, new drug approvals, and public health needs.

Benefits of NLEM

- Ensures availability of affordable medicines for all citizens.
- Helps in budget allocation for government hospitals and programs.
- Promotes prescription of rational and essential medicines only.
- Reduces treatment cost for patients.
- Strengthens national drug policy and public health infrastructure.

Offences and Penalties (Under DPCO 2013)

Offence	Penalty / Action
Selling drugs above ceiling price	Manufacturer must refund the overcharged amount with 15% interest
Non-compliance with NPPA orders	Legal action under Essential Commodities Act
Failure to submit price data	Fine or suspension of license
Misleading labeling or overpricing	Penal prosecution by government

Salient Features of DPCO 2013

1. Linked to NLEM 2011/2022 – only essential medicines are price-controlled.
2. Market-based pricing instead of cost-based pricing.
3. Annual price revision linked to WPI (Wholesale Price Index).
4. Transparent calculation method for ceiling prices.
5. Regulation of both manufacturers and importers.
6. Consumer protection against unethical pricing.
7. Online monitoring system for price submission and revision.