Drug Price control Order

Drugs Price Control Order (DPCO-2013), Introduction

- The Drugs Price Control Order (DPCO) was first introduced in 1970 and has been updated several times, with the latest version being the DPCO, 2013.

Introduction

- The Drug Price Control Order (DPCO) is a legal mechanism implemented by the Government of India to ensure the availability of essential medicines at affordable prices by regulating the prices of drugs.
- The DPCO is issued by the government under the powers granted by the Essential Commodities Act, 1955.

Purpose of DPCO:

- It is a legal framework that regulates the prices of drugs in India.
- It specifically applies to drugs listed in the National List of Essential Medicines (NLEM) to ensure their availability and affordability.
- It grants NPPA the authority to enforce price controls.

Scope of DPCO, 2013:

- Covers scheduled formulations listed in NLEM and non-scheduled drugs under specific regulations.
- Ensures prices are fixed based on market-based pricing mechanisms rather than cost-based approaches.

Historical Background

Pre-DPCO Scenario:

- In the 1960s and 1970s, India was heavily dependent on **foreign pharmaceutical companies**.
- Drug prices were **unregulated**, leading to **exorbitant costs**, especially for essential medicines.
- The **Hathi Committee (1975)** strongly recommended the regulation of drug prices and the promotion of domestic manufacturing.

Key Milestones:

Year	Version	Key Features
1970	First drug policy	Emphasis on self-reliance
1979	DPCO 1979	First formal price control mechanism
1987	DPCO 1987	Broader list of controlled drugs

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1995	DPCO 1995	Introduced Scheduled Drugs list
2013	DPCO 2013	Shifted to market-based pricing, aligned with NLEM
2023	DPCO 2023 (Proposed amendments)	Further strengthening of price monitoring

Recent Developments (As of 2023–2025)

A. NLEM 2022 Update

- Updated list of essential medicines, including **antivirals**, **cancer drugs**, **insulins**, etc.
- DPCO adapted to this list for new ceiling prices.

B. Proposal for DPCO 2023

- Still under review (as of 2025).
- Likely features:
  - More flexible pricing for innovation-driven drugs.
  - Dynamic pricing tools using real-time market data.
  - Expanded digital surveillance and AI-based price monitoring.

Successes and Limitations of DPCO

Successes:

- Price control on essential medicines improved **affordability**.
- Helped curb **exploitation by large pharma companies**.
- Promoted **transparency** in the pharmaceutical market.

Limitations:

- **Limited scope**: Only essential drugs are covered.
- Some manufacturers **discontinue low-profit drugs**.
- No direct control over **hospital/doctor margins** or **private pharmacy markups**.
- Enforcement in **remote areas is weak**.

Key Definitions in DPCO, 2013

1. Scheduled Drug:

- A drug listed in **Schedule I** of DPCO, derived from the **National List of Essential Medicines (NLEM)**.
- These drugs are subject to **price control**.

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2. **Non-Scheduled Drug:**
   - Drugs that are **not listed** in **Schedule I** and are **not under price control**.
   - NPPA monitors their price increases, which cannot exceed **10% annually**.
3. **Ceiling Price:**
   - The **maximum price** at which a **scheduled drug** can be sold.
4. **Formulation:**
   - A **medicine** prepared in a specific form (tablet, capsule, syrup) containing one or more **active pharmaceutical ingredients (APIs)**.
5. **Bulk Drug:**
   - The **active ingredient** used in the formulation of medicine, without processing into the final product.
6. **Retail Price:**
   - The **maximum selling price** of a formulation (including taxes) set by the **manufacturer** but regulated under DPCO.
7. **National List of Essential Medicines (NLEM):**
   - A **list of essential medicines** defined by the government based on **public health importance** and **cost-effectiveness**.

Pricing Mechanisms under DPCO, 2013

Sale Prices of Bulk Drugs:

- Bulk drugs (active pharmaceutical ingredients) are the **raw materials** used to make medicines.
- Prices of bulk drugs can only be fixed or regulated by NPPA if they are included in the Schedule I list of DPCO.
- Non-scheduled bulk drugs are not regulated, but their prices are monitored for unreasonable increases.

Retail Price of Formulations:

- The retail price of medicines is calculated using the market-based pricing formula introduced in DPCO, 2013, as opposed to the earlier cost-based pricing method.
- **Formula for Retail Price:**

  Retail Price = (Average Price of the Drug) + (16% Margin for Retailer)
- NPPA calculates the average price based on the prices of all brands having at least 1% market share.

Retail Price and Ceiling Price of Scheduled Formulations:

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1. **Ceiling Price:**
   - NPPA fixes the **maximum ceiling price** of **scheduled formulations** to prevent overcharging.
   - Manufacturers cannot sell the drug at prices higher than the ceiling price.
2. **Revisions of Prices:**
   - NPPA periodically **reviews and revises** the ceiling prices based on **inflation** and **market data**.
3. **Exemptions:**
   - New drugs with **patents or innovation** are exempted from price control for **5 years** to promote **R&D**.

Monitoring Non-Scheduled Drugs:

- For **non-scheduled drugs**, NPPA monitors price increases and imposes restrictions if the price increase exceeds **10% per year**.

Offences and Penalties under DPCO, 2013

Offences:

1. **Overcharging Beyond Ceiling Price:**
   - Selling a scheduled formulation at a price higher than the **ceiling price**.
2. **Failure to Display Price Lists:**
   - Manufacturers and retailers must **display price lists** prominently.
3. **Non-compliance with Reporting Requirements:**
   - Failure to submit **pricing data** to NPPA.
4. **False Information:**
   - Providing **incorrect or misleading data** regarding pricing or sales.

Penalties:

1. **Refund with Interest:**
   - Overcharged amounts must be **refunded to consumers** with **15% interest**.
2. **Prosecution:**
   - Legal action, including **fines** and **imprisonment**, can be taken for serious violations.

National List of Essential Medicines (NLEM)

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