National Pharmaceutical Pricing Authority (NPPA)

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Introduction:

Established: August 29, 1997

Under: Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

Legal Authority: Derived from the Essential Commodities Act, 1955 through DPCO (Drugs Price Control Orders)

Objectives of NPPA

1. **To ensure availability of essential medicines** at **affordable prices** to all.
2. To **fix and regulate prices** of **scheduled (essential) drugs** under the DPCO.
3. To **monitor prices** of **non-scheduled drugs** and ensure no excessive price rise.
4. To implement and enforce provisions of the **DPCO, 2013**.
5. To maintain and update the **database of pharmaceutical manufacturers**.
6. To collect and analyze market data on:
    - Production
    - Imports/exports
    - Market share
    - Profitability
7. To deal with complaints related to **overcharging** or **violation of pricing norms**.
8. To **implement Drug Price Control in a transparent, consistent and scientific manner.**

Drugs Price Control Order (DPCO) – 2013

Issued Under: Section 3 of the Essential Commodities Act, 1955

Replaces: DPCO, 1995

Enforced by: NPPA

Objectives of DPCO 2013

- Ensure availability of essential medicines at **affordable prices**
- Promote rational use of drugs

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- Enable industry to grow while ensuring **reasonable returns**
- Reduce regional disparities in drug availability and pricing
- Align with the **National Pharmaceutical Pricing Policy (NPPP), 2012**

Key Definitions under DPCO 2013

Understanding certain key definitions is essential for interpreting the law:

1. **Scheduled Formulation**
   - A formulation that contains one or more active ingredients included in the **National List of Essential Medicines (NLEM)** and listed in **Schedule I** of DPCO.
2. **Ceiling Price**
   - The **maximum price** that can be charged for a **scheduled formulation** by any manufacturer.
   - Determined based on the **market-based pricing formula**.
3. **Retail Price**
   - The price at which a drug formulation is sold to the ultimate consumer (includes taxes).
4. **Bulk Drug (Active Pharmaceutical Ingredient - API)**
   - A drug substance used in the manufacture of formulations. It is the active component without excipients or delivery systems.
5. **Formulation**
   - A finished pharmaceutical product containing one or more active ingredients with or without excipients, presented in a specific dosage form.

Pricing Under DPCO, 2013

Sale Prices of Bulk Drugs

- While **bulk drugs** themselves are **not price-controlled under DPCO, 2013**, the **formulations** prepared from them **may be** if the formulation is part of the NLEM.
- Earlier DPCOs like 1995 controlled prices of many bulk drugs, but the 2013 version shifted focus more on formulations.
- However, bulk drug manufacturers must submit:
  - Production cost data
  - Import/export data
  - Manufacturing capacity

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- This helps NPPA **calculate cost-based ceiling prices** if required under **exceptional circumstances**.

Retail Price of Formulations (Non-Scheduled Drugs)

For Non-Scheduled Formulations:

- Manufacturers can fix the **retail price**.
- But the price **cannot be increased by more than 10% annually** (as per WPI – Wholesale Price Index).
- NPPA **monitors** these prices.

Retail Price Fixation Mechanism:

- Based on manufacturer’s **application** to NPPA.
- Includes cost of production, packaging, marketing, and a **reasonable profit margin**.

Retail Price and Ceiling Price of Scheduled Formulations

Ceiling Price (Scheduled Drugs):

- NPPA calculates **ceiling price** using the **Market-Based Pricing (MBP)** method.
- Based on average price of all brands having **1% or more market share**.

Formula:

Ceiling Price = Average price to retailer of all major brands + Retailer margin (16%)

Retail Price:

- Once ceiling price is declared, the company **cannot sell above it**.
- They can **choose a price equal to or lower than** the ceiling price.

Retailer Margin:

- Maximum 16% for scheduled formulations.
- Trade margins are strictly controlled under DPCO for scheduled drugs.

Pharmaceutical Policy 2002

Background

- Preceded the **National Pharmaceutical Pricing Policy (NPPP), 2012**
- Aimed to balance the **growth of the pharmaceutical industry** with the **need for price control**

Objectives

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- Ensure availability of quality medicines at **reasonable prices**
- Encourage indigenous production and **self-reliance**
- Promote research and development
- Encourage exports
- Streamline and reduce price control to only **essential medicines**

Key Features

- Classification of drugs into 3 categories:
  - **Life-saving and essential drugs** (under strict price control)
  - **Drugs of moderate importance** (partially controlled)
  - **Decontrolled drugs** (free from price control)
- Focused on **R&D encouragement** and reduction of manufacturing cost through bulk drug production

Limitations

- Considered outdated by the time of its implementation
- Did not fully align with the need for **dynamic price regulation**
- Eventually replaced by the **National Pharmaceutical Pricing Policy, 2012**, which led to DPCO 2013

National List of Essential Medicines (NLEM)

Overview

- The National List of Essential Medicines (NLEM) is a key policy tool introduced by the **Ministry of Health and Family Welfare** to promote equitable access to medicines across India.
  - **Introduced:** 1996
  - **Revisions:** 2003, 2011, 2015, and most recently in **2022**
  - **Developed by:** Core Committee including representatives from **ICMR**, **AIIMS**, **CDSCO**, **NPPA**, and others
  - **Based on:** The **WHO Model List of Essential Medicines**

Purpose and Objectives

- To identify medicines that meet the **priority healthcare needs** of the population
- To serve as a **guiding framework** for:

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