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Pharmacy Law & Ethics

CHAPTER 9

National Pharmaceutical Pricing Authority



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

Government of India
Resolution dated
29 AUGUST 1997

ESTABLISHMENT

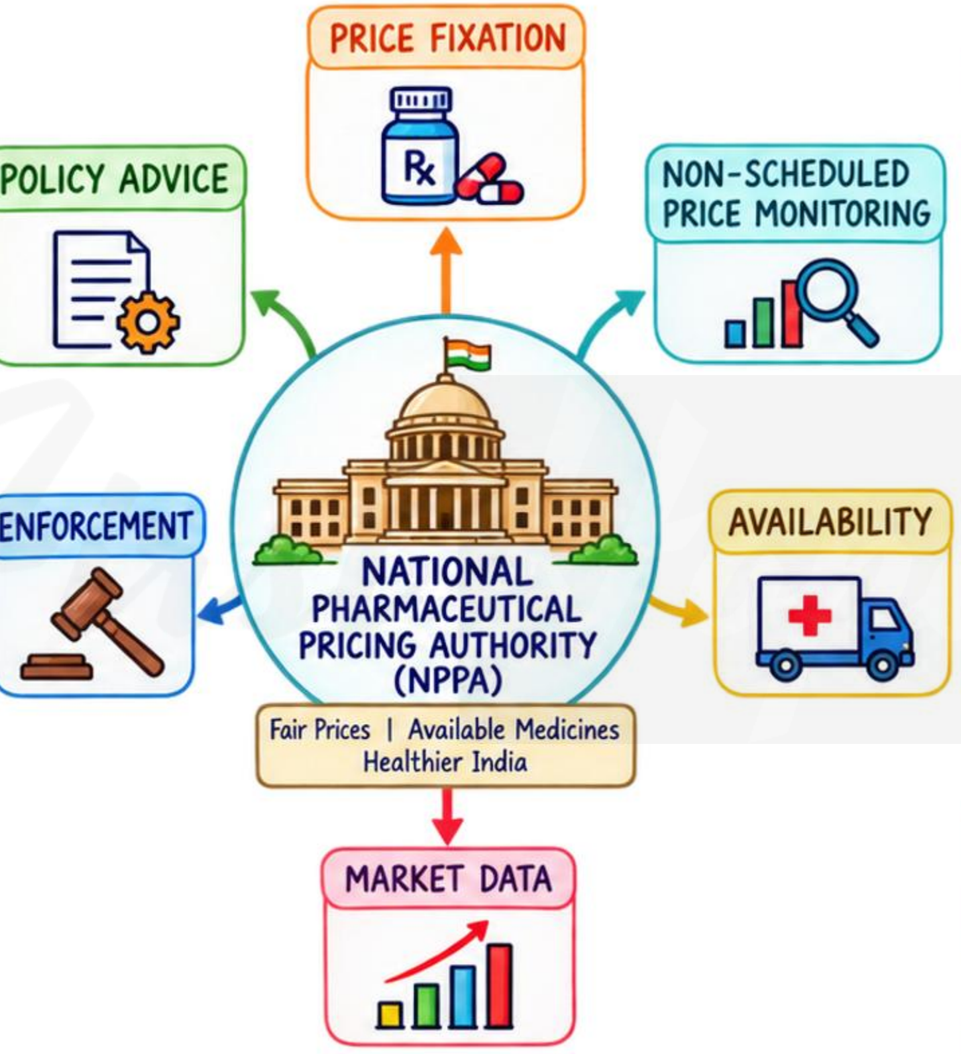
National Pharmaceutical Pricing Authority (NPPA) was constituted by Government of India Resolution dated 29 August 1997.
It is an attached office of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

CORE PURPOSE

Ensure that medicines remain available and accessible at reasonable prices while implementing the national drug-pricing framework.

LEGAL POSITION

NPPA exercises powers delegated by the Central Government under the Essential Commodities Act, 1955 and DPCO.



MAIN FUNCTIONS

- Fix and revise ceiling prices of scheduled formulations under DPCO.
- Fix retail prices of specified "new drugs".
- Monitor MRP movement of non-scheduled formulations.
- Implement and enforce the Drugs (Prices Control) Order.
- Monitor availability, identify shortages and take remedial steps.
- Collect data on production, imports, exports, market share and profitability.
- Examine overcharging and other price violations; handle related legal matters.
- Undertake pricing studies and advise the Central Government on drug policy.

PUBLIC HELP

Consumers can report overpricing, refusal of sale or non-availability through NPPA's grievance system, including Pharma Jan Samadhan.

EXAM KEY

NPPA regulates prices and availability; policy itself is framed by the Government, with NPPA providing inputs.

CITIZENS → Report overpricing, refusal of sale or non-availability → NPPA's grievance system, including Pharma Jan Samadhan. → NPPA Takes action on complaints

DRUGS PRICE CONTROL ORDER (DPCO) – 2013

LEGAL BASIS

Drugs (Prices Control) Order, 2013 was issued by the Central Government under Section 3 of the Essential Commodities Act, 1955.
Notification: S.O. 1221(E), dated 15 May 2013.
It superseded DPCO, 1995 for future operation.

POLICY BASE

National Pharmaceuticals Pricing Policy (NPPP), 2012 supplied three central principles:

1. ESSENTIALITY – focus on medicines needed for priority health care.
2. FORMULATION PRICE CONTROL – regulate finished dosage forms rather than routine cost-based control of bulk drugs.
3. MARKET-BASED PRICING – use observed market PTR data for ceiling-price calculation.

ESSENTIAL COMMODITIES ACT 1955
↓
NPPP 2012
↓
DPCO 2013
↓
NPPA ACTION



HISTORICAL TRANSITION

DPCO 1995 → DPCO 2013

DPCO, 1995 replaced by DPCO, 2013.

CURRENT-LAW NOTE

DPCO 2013 has been amended several times, including in 2026. Always read it with the latest amendments.

WHAT DPCO 2013 DOES

- Defines scheduled and non-scheduled formulations.
- Provides the market-based ceiling-price formula.
- Controls MRP of scheduled formulations through the notified ceiling price.
- Provides retail-price fixation for specified new drugs.
- Monitors price rise of non-scheduled formulations.
- Provides for price lists, records, availability monitoring and recovery of overcharged amounts.

SCHEDULE I

Contains the medicines/formulations brought under scheduled price control. It is revised by Gazette notification when the NLEM-based list is updated.

ENFORCEMENT CHAIN

Essential Commodities Act → DPCO → delegated powers → NPPA notifications and enforcement.

KEY DEFINITIONS UNDER DPCO 2013

SCHEDULED FORMULATION

A formulation included in the First Schedule of DPCO, whether referred to by generic version or brand name.

NON-SCHEDULED FORMULATION

A formulation not included in Schedule I.

CEILING PRICE

The maximum price fixed by the Government for a scheduled formulation., excluding applicable local taxes. MRP cannot exceed the ceiling price plus applicable local taxes.



PRICE TO RETAILER – PTR

Price at which a drug is sold to a retailer. It includes duties but excludes local taxes.

RETAIL PRICE

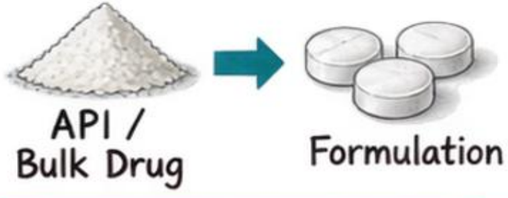
Under DPCO, this is the price fixed by the Government for a "new drug" under paragraph 5. It is not merely a general synonym for the shop price.

NEW DRUG – DPCO MEANING

A formulation launched by an existing manufacturer of a scheduled formulation by combining a listed medicine with another medicine, or by changing its listed strength or dosage, as defined in DPCO.

ACTIVE PHARMACEUTICAL INGREDIENT / BULK DRUG

The active substance used as such or as an ingredient in a formulation and conforming to applicable drug standards.



FORMULATION

A medicine processed into a dosage form for, or capable of, internal or external use in diagnosis, treatment, mitigation or prevention of disease.



CORRECTION TO SOURCE

DPCO 2013 mainly controls scheduled formulations; it does not generally fix every bulk-drug price.

PTR: Taxes Excluded
MRP: Taxes Included

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