

NPPA and DPCO

September 18, 2020

National Pharmaceutical Pricing Authority (NPPA) was **constituted in 1997** as an **attached office of the Department of Pharmaceuticals (DoP)**, Ministry of Chemicals & Fertilizers as an independent regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

- It **fixes/ revises the prices of controlled bulk drugs and formulations** and to enforce prices and availability of the medicines in the country, under the **Drugs (Prices Control) Order, 1995**.
- The organization is also entrusted with the task of **recovering amounts overcharged by manufacturers** for the controlled drugs from the consumers.
- It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

Functions of NPPA

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To monitor the availability of drugs, **identify shortages**, if any, and to take remedial steps.
- To collect/ **maintain data on production, exports and imports, market share** of individual companies and profitability of companies for bulk drugs and formulations.
- To undertake and/ or **sponsor relevant studies in respect of pricing of drugs/** pharmaceuticals.
- To **render advice to the Central Government** on changes/ revisions in the drug policy.
- To render **assistance to the Central Government in the parliamentary matters** relating to the drug pricing.

Drug Price Control Order

- The Drugs Prices Control Order, 1995 is an order issued by the Government of India under **Sec.3 of Essential Commodities Act, 1955** to regulate the prices of drugs.
- The Order provides a list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by the government and penalties for contravention of provisions.
- For the purpose of implementing provisions of DPCO, powers of the government have been vested in NPPA.
- All drugs marketed in the country aren't under price control. The **National List of Essential Medicines (NLEM) 2011** is adopted as the primary basis for determining essentiality, which constitutes the list of scheduled medicines for the purpose of price control.
- The DPCO 2013 contains 680 **scheduled drug formulations** spread across 27 therapeutic groups. However, the prices of other drugs can be regulated, if warranted in public interest.
- As per the provisions of DPCO, NPPA fixes the **ceiling price for medicines in the controlled category**. The ceiling price of a scheduled drug is determined by first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular drug formulation having a market share of 1% and above, and then adding a notional retailer margin of 16% to it.
- On April 1st 2020 **medical devices** were notified and all these devices shall be **regulated** by the Government of India **as drugs** aiming for effective control and price monitoring. Currently the Government is regulating 24 devices which are regulated as drugs under Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945.
- Of the above 4 are the medical devices scheduled for which ceiling prices had been fixed are: **cardiac stents; drug eluting stents, condoms and intrauterine devices**

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