Trade Margin Cap on Anti-Cancer Drugs

Why in news?

The National Pharmaceutical Pricing Authority (NPPA) has imposed a trade margin cap on 42 non-scheduled anti-cancer drugs.

What are scheduled and non-scheduled drugs?

- “Scheduled drugs” or “Scheduled formulations” are those medicines which are listed out in the Schedule I of Drug Price Control Order (DPCO) and on which price controls are applicable.
- Since 2013, scheduled drugs consist of the “Essential Medicines” declared so by the Government through its National List of Essential Medicines (NLEM).
- Any formulation based on combination of any one of the drugs appearing under NLEM can be subject to price fixation.
- In other words, NLEM forms the basis of deciding on the “Scheduled drugs”.
- On the other hand, non-scheduled formulations are medicines that are not under price control of NPPA.

- In this case, the Drug Prices Control Order, 2013 allows manufacturers to increase the MRP by 10% annually.
- So while essential medicines are subject to absolute price controls in the form of ceiling prices, the non-essential/non-scheduled medicines are subject to a managed price increase.

What is NPPA's present order?

- Currently, 57 anti-cancer drugs are under price control as scheduled formulations.
- Now, 42 non-scheduled anti-cancer medicines have been selected for price regulation, with MRP reduction up to 87%.
- These would cover more than 70 formulations and around 390 brands.
- Trade margins are capped at 30% of the MRP, or conversely a 43% mark-up on the price to the stockist (price at which manufacturers supply to retailers).
- The manufacturers of these 42 drugs have been directed not to reduce production volumes of brands under regulation.

Why is it significant?
Being non-scheduled, these 42 life-saving drugs do not fall under the ambit of price control.

The NPPA has thus invoked its extraordinary powers in public interest, under Para 19 of the Drugs (Prices Control) Order, 2013, for this move.

As per this, the Government may fix the ceiling price or retail price of any drug, whether scheduled or non-scheduled or a new drug, for such period as it may deem fit.

NPPA'S move is thus a new paradigm of regulation by the pharma industry.

**How will it benefit?**

- According to the NPPA, the rationalisation of trade margins will lead to an MRP reduction of 50-75% in the case of 124 brands.
- In the case of another 121 brands, the reduction will be 25-50% and up to 87% in some cases.
- The price rationalisation move is expected to benefit 22 lakh cancer patients in the country.
- This is likely to result in annual savings of approximately Rs. 800 crores to the consumers.
- Notably, the average out of pocket expenditure for cancer patients is 2.5 times that for other diseases.
- Out of pocket expenses in India account for nearly 70% of total healthcare expenses.
- Significantly, cancer care forces even middle-class households into debt and economic distress.

**Source:** Business Line, PIB, The Hindu

**Quick Facts**

**National Pharmaceutical Pricing Authority**

- National Pharmaceutical Pricing Authority (NPPA) was constituted through a Government of India Resolution in 1997.
- It is an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers.
- It works as an independent regulator for pricing of drugs and also ensures availability and accessibility of medicines at affordable prices.
- It implements and enforces the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.