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 7o 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.