Regulating drug prices

What is the issue?

Out-of-pocket expenditure on health is higher in India and hence more needs to be done to make medicines affordable.

How are prices regulated?

- The largest share of out-of-pocket expenditure on health is due to medicines in India (approximately 70%, according to the NSSO).
- This is a major access barrier to healthcare, especially for the poor.
- Thus, to make medicines affordable, the DPCO (Drug price control order) was made to control the prices of all essential medicines by fixing ceiling prices, limiting the highest prices companies can charge.
- The National List of Essential Medicines (NLEM) is drawn up to include essential medicines that satisfy the priority health needs of the population.
- The list is made with considerations of safety, efficacy, disease prevalence and the comparative cost-effectiveness of medicines.
- The list is updated periodically by an expert panel set up for this purpose under the aegis of the Ministry of Health and Family Welfare.
- This list forms the basis of price controls under the DPCO.

What is the mechanism for price capping?

- The NLEM 2015 contains 376 medicines on the basis of which the National Pharmaceutical Pricing Authority (NPPA) has fixed prices of over 800 formulations using the provisions of the DPCO.
- However, these formulations cover less than 10% of the total pharmaceutical market.
- The DPCO follows a market-based pricing mechanism.
- Accordingly, the ceiling price is worked out on the basis of the simple average price of all brands having at least 1% market share of the total market turnover of that medicine.

Have any other methods been used?

- Prior to 2013, the DPCO followed a cost-based pricing mechanism that was based on the costs involved in manufacturing a medicine along with reasonable profit margins.

- Health experts have argued that this policy resulted in comparatively lower prices than the current market-based policy.
- Since the implementation of the DPCO, 2013, the NPPA has made certain departures from the market-based pricing mechanism, which was found to be insufficient for ensuring affordability.
- This has been done through the use of special powers to act in public interest under Paragraph 19 of the DPCO.
- In 2013, the government had delegated these powers to NPPA to set the price cap of scheduled and non-scheduled drugs.
- These are the same powers NPPA used in 2017 to cap prices of cardiac drugs, stents and knee implants.

What is the case with cancer drugs?

- The government recently planned to cap the trade margins for highly priced drugs for cancer and rare diseases to bring down their prices.
- This is because of the recent amendments to the DPCO that exempted patented medicines and rare disease drugs from price controls.
- Under the amendment, a drugmaker who has brought in an innovative patented drug will be exempt from the price control regulations for 5 years from the date of marketing.
- Also, drugs for treating rare or "orphan" diseases too will be exempt from price control, with a view to encouraging their production.
- However, only MNCs are manufacturing orphan drugs at the moment; so lack of price control will have a detrimental effect on affordability.
- Along with that, cancer drugs are increasingly patented with no generic competition, putting them out of the reach of poor patients.
- Even the recent plan to cap trade margins will not sufficiently bring down prices.
- Thus, the government should take serious policy measures to ensure true affordability such as through price controls, implementation of the national rare disease policy and the use of legal flexibilities under patent law.

Source: The Hindu

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