RESEARCH PAPER

Control Drug Prices in India: Balancing Access, Innovation, and Policy Impact

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ABSTRACT

The DPCO was initially launched in 1970 under the Essential Commodities Act, and has since been amended numerous times to account for evolving economic conditions, public health requirements, and market forces. Every iteration of the DPCO has sought to balance making drugs affordable with fostering the development of the pharmaceutical sector. The current one—DPCO 2013, and its revisions thereafter—represents a radical departure from the past cost-based pricing to a market-based pricing system. It was done to enhance transparency and ease the process of price control.

Keywords: *DPCO act, DPCO 2022, DPCO 2013, Essential Commodities act, affordable healthcare, pricing policy, price control, NPPA*
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INTRODUCTION

Affordable healthcare is a key issue in a nation like India, where a significant portion of the population relies on out-of-pocket spending for medical care. To ensure that essential medicines remain affordable for the masses, the Indian government has taken several regulatory steps over the years. Among the most effective tools in this endeavor is the Drug Price Control Order (DPCO), which fixes price ceilings for specific medicines to check excessive pricing by manufacturers.

This research paper analyses the principal features of the latest DPCO, but also looks at the historical evolution of drug price regulation in India. It presents statistical information and cross-version comparisons in the DPCO in order to appreciate to what extent such policies have proved effective in securing affordable access to critical drugs. By reviewing the existing regulatory architecture as well as its change, this study proposes to shed light on challenges as well as possibilities in price control of medicines in India now.

HISTORY

DPCO 1974: Initially, the government had the overall control over the profits and prices of drug manufacturing industry and drugs by stipulating that when pre-tax profit of pharmaceutical companies exceeds 15% of their pharma sales, the surplus amount is deposited to the government. The freedom of deciding prices of the company's products was within the hands of the company so far as the surplus amount was given to the government.

DPCO 1979: The freedom of having to decide the prices of their products was soon snatched from the pharmaceutical companies on passing of this act. There were provisions made to keep the retail price of drugs under control by using the Maximum Allowable Post Manufacturing Expenses (MAPE) concept that set up limits to the ex-factory costs along with selling and distribution costs and set trade margins in retail and wholesale trades. The formula was as follows:

Retail price = (Material cost +Conversion Cost+ Packing Material Costs+ Packing Charge) X $(1+\frac{MAPE}{100})$ + excise duty

This version of DPCO act put about 370 drugs under price control while also separating them into 4 categories based on their use and importance.

DPCO 1987: This act was introduced to control the prices of essential drugs in India and was a cost-plus pricing regime, where drug prices were determined by the cost of production plus a fair margin of profit. The order covered both bulk drugs and formulations, with price regulation particularly focusing on firms with more than 10% market share. The initial list of 142 bulk drugs and approximately

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3,000 formulations were incorporated in the scheduled list, chosen on the basis of their essentiality and market presence. The government approval for pricing of scheduled drugs was required under the DPCO to ensure affordability, although the pharmaceutical industry criticized it for curbing profitability and innovation.

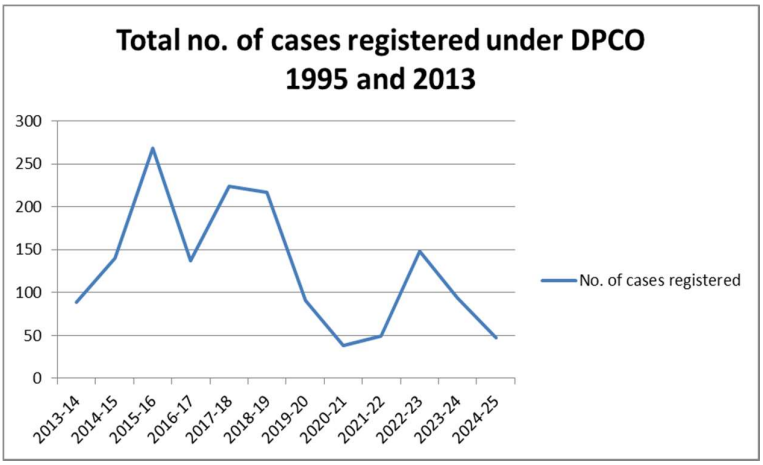
DPCO 1995: This version of DPCO act was released under the updated norms of drug policy released in 1994 that mainly focused on liberalizing the economy with abolishing industrial licensing and making the Indian market more attractive for foreign investors. This version of the DPCO act reduced the number of scheduled drugs from 142 to just 76 drugs. Also while fixing the maximum sale price of the bulk drug, the government had to provide either post-tax return of 14% on net worth or a return of 22% on capital employed, and the company can choose any one of the above mentioned post tax returns on their yearly returns.

DPCO 2002: The version of DPCO act was mainly focused on having the FDI (Foreign Direct Investment) companies enter the Indian market which changed the basis of having the DPCO act established by increasing the turnover limit of pharma companies along with share market relaxations, also the drugs that had a unit price less than Rs. 2 were also excluded from getting under price control. There were some exemptions made on drugs developed through indigenous R&D and New Delivery Systems. A shift in focus due to these newly introduced and amended parameters resulted in having the essential drugs fall out of price control and thus this version of DPCO act was never implemented.

After the unsuccessful implementation of DPCO 2002, the Supreme Court ordered a replacement for the Drug Policy1994 with the introduction of National Pharmaceutical Pricing Policy (NPPP) 2012 that is just a continuation of the previously issued drug policies. The Supreme Court also planned to get the essential medicines revised by the Ministry of Health and Family Welfare in the National List of Essential Medicines (NLEM) list released in 2003 which was further revised in 2011 and 2021, adding and removing the drugs depending upon their essentiality. [4,6]

STATISTICAL DATA

Based on the report published by NPPA on its official website, the following graph was plotted that includes the number of cases registered under DPCO 1995 and 2013, those that violate the basic principle of the act that focuses on having drug prices under control. The graph shows an initial peak that took place as soon as the DPCO 2013 amendment was passed out and a comparatively sharp decline along the concurrent years as a result of the stricter action.



DRUG PRICE CONTROL ORDER 2013

DPCO 2013 and 2022 are both currently used to have the essential drugs under price control. Drugs are accepted as an essential commodity by the Essential Commodity Act 1955, thus it is essential to have stricter laws guarding the adequate pricing of a drug considering the profit margin of the companies, commonality of the drug and also about the disease it is being used for. DPCO acts of 2013 and 2022 versions have adopted a unique way to have the essential drugs listed that is by giving authorization to NLEM (National List of Essential Medicines) that lists out the essential drugs required to the individuals. [2,4]

Objectives:

1. Affordability of essential drugs through a market-based pricing mechanism where ceiling prices are decided based on the simple average of prices of brands with at least 1% market share (Department of Pharmaceuticals, 2013).
2. Promoting universal access to medicines through the regulation of drugs in the NLEM to strengthen public health delivery.
3. Transparency and predictability in prices through standardized methodologies carried out by the National Pharmaceutical Pricing Authority (NPPA, 2014).

4. Reduction of out-of-pocket expenditure on health by placing ceilings on the prices of high-demand formulations.
5. Promotion of rationality in the use of medicines and generics and avoidance of unnecessary and overpriced drug combinations.
6. The policy's alignment with public health priorities, including those of vulnerable populations.
7. Balancing affordable medicines with economic viability of the pharmaceutical industry.[2,4,7]

DRUG PRICE CONTROL ORDER 2022: [3, 9, 10]

The DPCO 2022 is an enabling legal instrument implemented by the Government of India under the Essential Commodities Act of 1955. One of the most striking features of this order is the continued regulation of the prices of medicines listed under the National List of Essential Medicines (NLEM) to keep life-saving drugs within the economic reach of the common man. For the first time, DPCO 2022 also covers patented drugs such as those used in TB and HIV/AIDS therapy under price control, marking a sharp policy change in an attempt to bring life-saving therapies under an affordable price range. Moreover, the order claims a reduction in the price by 50% once the patent period of drugs is over and a ceiling price revision after one year after the introduction of drugs by way of actual market-based data. This stimulates greater 8.

affordability of off-patented drugs. Furthermore, DPCO 2022 introduces much clearer and more transparent price-fixation methodologies, which further improves predictability and accountability in the system. It also has the NPPA's assessment to see if the policies are being implemented, if they are complied with, and prevent exorbitant pricing, unless there is any shortage in the supply to ensure continuous supply of life-saving drugs in the Indian pharmaceutical market.

Objectives:

1. Ensure access to key medicines at reasonable prices.
2. Control and regulate drug prices in the National List of Essential Medicines (NLEM).
3. Have a market-based pricing mechanism to enhance fairness and transparency.
4. Promote healthy competition in the pharmaceutical industry without stifling innovation.
5. Avoid hoarding, black marketing, and illegal pricing.
6. Indirectly support the quality of drugs by ensuring fair prices don't compromise manufacturing quality.
7. Give power to the National Pharmaceutical Pricing Authority (NPPA) to track, regulate, and enforce prices of drugs.

Comparison stating the subtle differences in the two recent versions of the act: [2, 3, 4]

DPCO 2013	DPCO 2022
It uses the pricing mechanism of Simple Average Price (SAP) of brands with >1% market share	Pricing mechanism used here is Weighted Average Price (WAP) considering the market structure
Focuses primarily on essential medicines in NLEM	Has an expanded coverage, including more drugs for chronic diseases and orphan drugs
Prices are fixed based on market share of existing brands	Price fixation is dynamic, and is based on market prices and CPI inflation
Annual adjustment is based on Wholesale Price Index (WPI)	Frequent adjustments is based on Consumer Price Index (CPI)
It has limited regulation for new and patented drugs	Unlike its earlier version, there are clearer and stricter pricing for new and patented drugs
Does not cover orphan drugs under price control	Orphan drugs are included under price control for affordability
It is less flexible, with longer delays in adjustments	More transparent and flexible, with faster response times and greater market sensitivity
Primarily based on market share of existing drugs	More comprehensive market-based pricing, considering overall competition

*Orphan drugs: these are the drugs that are used for treatment of rare diseases and are generally exempt from price control to bring about more of their development.

*WPI (wholesale price index): It is basically used to annually revise the ceiling prices of scheduled formulations, with the annual increase based on the WPI for the preceding calendar year, notified by the government on April 1st.

*CPI (consumer price index): It is the average amount paid by the consumers to the companies in exchange for the products produced

Improvements of DPCO 2022 over 2013 edition: [3, 4]

- DPCO 2022 encompasses a wider range of essential medicines, including those used in the treatment of chronic and rare diseases which favors greater price controls in healthcare areas.

- The weighted average price (WAP) as per DPCO 2022 reflects the actual market prices of medicines better than the simpler and less reflective average price methodology of DPCO 2013.
- DPCO 2022 ensures that new and patented medicines are priced fairly and prevents exploitation of consumers and patients by pharma companies. The new pricing formula aligns more closely with public health objectives.
- DPCO 2022 gives NPPA a more efficient mechanism to act. The new provisions also ensure that the enforcement of the price mechanism is more transparent and responsive.
- The CPI-based adjustment for medicines under DPCO 2022 will allow the new pricing mechanism to reflect new economic realities and consumer inflation more effectively.
- The inclusion of orphan drugs (medicines for rare diseases) under the price control mechanism is a significant step toward ensuring affordable healthcare for more patients.

The 2022 edition of DPCO Act is only an amendment to get rid of any drawbacks in the previous version and thus the older version is in current use that applies all the necessary rules to the companies in order to keep the prices in check.

Penalties: [11]

- Penalties, on trespassing the law in any form, include imprisonment or fine and cancellation of the company's license.
- DPCO act was first introduced in 1970 and was later revised in the years 1979, 1987, 1995, 2013, and the current edition 2022 which helps in the regulation of drug prices and accordingly prosecutes those who go against the said rules.
- Penalty: Those that do not adhere to the rules of the DPCO Act are liable to penalties as mentioned in the essential commodity act. Drugs being an essential commodity to the masses and also quite susceptible to contamination or any other malpractices, it is necessary to impose strict actions on its manufacturing practices. Penalties such as imprisonment for a minimum of 3 months that may be extended up to 7 years and fine may be imposed on those found guilty of their offence in this regards.

REFERENCES

1. Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals.2013. *Drug Price Control Order (DPCO) 2013*. *The Gazette of India: Extraordinary, Part II, Section 3(ii)*, May 15, 2013.
2. Ministry of Chemicals and Fertilizers, Government of India. 2013. *Drug Price Control Order (DPCO) 2013*.
3. Ministry of Chemicals and Fertilizers, Government of India. 2022. *Drug Price Control Order (DPCO) 2022*.
4. National Pharmaceutical Pricing Authority (NPPA). *Official Website*.
5. Kumar, V., N. V. Gupta, and K. A. Kumar. 2014. "A Comparison between Old and Latest Systems in DPCO." *International Journal of Pharmaceutical Sciences Review and Research* 6 (2): 19–20.
6. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. (2012). *National Pharmaceutical Pricing Policy 2012: A review*. Government of India.
7. National Pharmaceutical Pricing Authority (NPPA). (2014). *Compendium of Orders and Guidelines under DPCO, 2013*. Government of India.
8. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. *Drug Price Control Order, 2013*. Government of India, 2013.
9. *Nishith Desai Associates.* "India Introduces DPCO 2022 and Updates NLEM: A Shift in Drug Price Control." 2022,
10. *National Pharmaceutical Pricing Authority (NPPA). Official Website*.
11. Government of India. 1955. *The Essential Commodities Act, 1955*. New Delhi: Ministry of Law and Justice.