



Fixation and Regulation of Prices of Drugs

प्रविष्टि तिथि: 07 AUG 2026 2:57PM by PIB Delhi

Prices of drugs are regulated as per the provisions of the Drugs (Prices Control) Order 2013 (DPCO, 2013) which has been promulgated based on the principles of the National Pharmaceutical Pricing Policy, 2012. National Pharmaceutical Pricing Authority (NPPA) fixes ceiling prices of formulations specified in Schedule-I to DPCO, 2013 in accordance with the provisions of DPCO based on market data and retail price of a new drug as defined under 2(1)(u) of DPCO, 2013 that is applicable to the applicant manufacturer and marketer, who are required to sell the new drug within the price notified by NPPA. In case of non-scheduled formulations, a manufacturer is required to not increase MRP of a non-scheduled drug by more than 10% of MRP during the preceding 12 months.

As a transparency measure, a draft version of the price calculation sheets for the proposed revised price notifications, are uploaded on the website of NPPA for 10 working days to invite comments from stakeholders. Only after taking into account comments received and any additional data received within the said time period, NPPA finalises ceiling and retail prices. Thus, the entire procedure of price fixation is available in the public domain, which ensures transparency and accountability of the process. All price notifications issued by NPPA are available on its website (<https://nppa.gov.in>).

NPPA monitors the compliance with the provisions of the DPCO, 2013 and takes appropriate action in cases of overcharging and other violations, in accordance with the provisions of DPCO, 2013, based on references received from various sources, including Price Monitoring and Resource Units set up in States, State Drugs Controllers, samples purchased from open market, reports from market database and complaints lodged through various grievance redress channels. In addition, to prevent overpricing, DPCO 2013 requires every manufacturer of a formulation to print the maximum retail price on the label of the container of such formulation. Further, no person is permitted to sell any formulation to any consumer at a price exceeding the price specified on the current price list or price indicated on the label of the container or the pack thereof, whichever is less.

With the aim to prevent unethical marketing and ensuring responsible promotion of pharmaceutical products by regulating interactions between doctors/registered medical practitioners (RMPs) and representatives of pharmaceutical companies, the DoP, on 12.3.2024, has issued the Uniform Code of Pharmaceuticals Marketing Practices 2024. The code outlines guidelines regarding promotion of drugs among doctors/RMPs. Pharmaceutical companies are accountable for the actions of their medical representatives and other employees. The code prohibits provision of gifts, monetary benefits and hospitality to doctors and their family members by pharmaceutical companies. It includes requirements for pharmaceutical companies to self-declare adherence to the code and disclose expenditures related to conferences, seminars and workshops organised for continuing medical education and continuing professional development. Companies may undergo independent, random or risk-based audits. The code establishes a two-layer complaint adjudication process, with appeals handled by the Department of Pharmaceuticals. Penalties under the code include the following:

- i. Reprimand to the pharmaceutical entity and publication of full details thereof;
- ii. Recovery of money or items given in violation of the code by the pharmaceutical entity from the persons concerned and notification of the action taken to the Ethics Committee under the code;
- iii. Issuance of a corrective statement in the media, if promotional material issued therein does not comply with the requirements specified in the code; and
- iv. Pharmaceutical companies may face action under existing laws by relevant government departments, based on violations detected during administration of the code.

For expenditure incurred by pharmaceutical companies on promotional activities to be tax deductible under the Income-tax Act, 1961, the same has to be in accordance with the guideline contained in the Uniform Code for Pharmaceutical Marketing Practices, 2024 and the provisions of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Thus, promotional expenditure incurred by pharmaceutical companies is subject to regulation.

In addition to regulating the prices of drugs under DPCO, 2013, various other measures have been taken by the Government to improve the access of medicines at affordable rates to the common man which, *inter alia*, include the following:

- i. The Government has launched the Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme under which quality generic medicines is provided through more than 20,000 Janaushadhi Kendras at rates that are typically 50% to 80% cheaper than branded medicines.
- ii. Under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) of the Department of Health and Family Welfare, health assurance/insurance cover of ₹5 lakh per family per year is provided for secondary or tertiary care hospitalisation, including for medicines.
- iii. Under the Free Drugs Service Initiative of the National Health Mission, essential medicines list recommended under the Indian Public Health Standards (IPHS) are made available free of any charge at public health facilities ranging from Primary Health Centres (PHCs) to district hospitals across the country.
- iv. Under the Amrit (Affordable Medicines and Reliable Implants for Treatment) initiative of the Department of Health and Family Welfare, affordable medicines are provided for the treatment of cancer, cardiovascular and other diseases, implants, surgical disposables and other consumables etc., at an average discount of up to 50% on market rates through AMRIT Pharmacy stores set up in number of hospitals and healthcare institutions.
- v. Financial assistance is provided to poor patients belonging to families living below the poverty line, who suffer from major life-threatening diseases including cancer, under the umbrella scheme of Rashtriya Arogya Nidhi and the Health Minister's Discretionary Grant.

This information was given by Minister of State for Chemicals and Fertilizers, Smt. Anupriya Patel, in a written reply in the Lok Sabha today.

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