GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION No. 28*
TO BE ANSWERED ON THE 04TH FEBRUARY 2025

Lack of transparency in Pharma industry

28 Shri Sanjay Raut:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) the manner in which Government is addressing the lack of transparency in the pharma industry regarding production costs, profit margins and pricing strategies;
(b) whether there are penalties for pharmaceutical companies or chemists engaging in unethical profiteering practices;
(c) the reasons due to which the pharma companies are allowed to spend exorbitant amounts on marketing, making essential medicines unaffordable;
(d) the steps being taken to cap marketing and promotional expenses to reduce the burden on patients; and
(e) the plans to adopt international best practices and regulations to ensure that healthcare and medicines remain affordable and accessible to all citizens in the country?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

(a) to (e): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO THE RAJYA SABHA STARRED QUESTION NO. *28 (13TH POSITION) FOR ANSWER ON 4.2.2025, RAISED BY SHRI SANJAY RAUT, REGARDING "LACK OF TRANSPARENCY IN PHARMA INDUSTRY"

(a): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes ceiling prices under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013) in respect of the drugs specified in Schedule-I to DPCO, 2013. Manufacturers of scheduled medicines (both branded and generic) are required to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by NPPA. In addition, NPPA fixes the retail price of new drugs as defined in DPCO, 2013. The retail price of a new drug 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 at liberty to fix the maximum retail price (MRP) of drugs launched by it. However, as per DPCO, 2013, a manufacturer is required to not increase MRP of a non-scheduled drug by more than 10% of MRP during the preceding 12 months.

NPPA monitors the prices of drugs and takes action against overcharging under relevant provisions of DPCO, 2013. Further, as a transparency measure, a draft version of the price calculation sheets for the proposed revised price notifications, including wherever applicable, the price to retailer (PTR) and moving annual turnover (MAT) values adopted for calculations, 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 (www.nppaindia.nic.in).

(b): With the aim of preventing unethical marketing and ensuring responsible promotion of pharmaceutical products by regulating interactions between doctors / registered medical practitioners (RMPs) and representatives of pharmaceutical companies, the Department of Pharmaceuticals, 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.

(c) and (d): Pharmaceutical companies cannot engage in advertising of any drug for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. The said Schedule covers most of the prevalent diseases, disorders and conditions and, therefore, pharmaceutical companies have to rely on doctors/RMPs to promote their products. The doctors themselves may not have knowledge of all developments in the field of drugs and, therefore, interaction between them and pharmaceutical companies is necessary. 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 guidelines 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.

(e): The Uniform Code for Pharmaceutical Marketing Practices, 2024 draws upon the Forty-first World Health Assembly resolution of 1988 on ethical criteria for medicinal drug promotion. The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of healthcare through rational use of medicinal drugs.

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