GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 194
TO BE ANSWERED ON THE 04TH FEBRUARY 2025

Regulating unethical practices in Healthcare and pharma sector

194 Shri Sanjay Raut:

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

(a) the actions Government is taking to dismantle the nexus between pharmaceutical companies, hospitals and doctors that leads to inflated prices for medicines;
(b) whether there are any ongoing investigations to examine allegations of profit-sharing, kickbacks and unethical practices within the healthcare sector;
(c) whether Government is planning to introduce stricter guidelines or amendments to the Drugs and Cosmetics Act to better regulate drug pricing and ensure ethical practices within the pharmaceutical industry; and
(d) the measures being implemented to ensure that doctors prescribe medicines based on genuine medical need rather than financial incentives from pharmaceutical companies?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): 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.

Further, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 made under the Indian Medical Council Act, 1956 provides the code of conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry.

(b): No investigation relating to violation of the provisions of the Uniform Code of Pharmaceuticals Marketing Practices 2024 is currently in progress.

(c): There is no proposal such amendments to the Drugs and Cosmetics Act, 1940.

(d): Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 provides that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is rational prescription and use of drug. Further, the Medical Council of India issued circulars dated 22.11.2012, 18.1.2013 and 21.4.2017 directing all registered medical practitioners to comply with the aforesaid provisions.

The National Medical Commission Act, 2019 empowers the appropriate State Medical Councils or the Ethics and Medical Registration Board of the National Medical Commission to take disciplinary action against a doctor for violation of the provisions of the aforesaid regulations. Further, States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

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