GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 838
TO BE ANSWERED ON 30th July, 2024

Monitoring mechanism for price rise of medicines

838 # Shri Neeraj Dangi:

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

(a) the details of the total number of medicines covered under the Drug Prices Control Order (DPCO) by Government;
(b) whether increase in prices of medicines has been noticed every year under DPCO, if so, the details of drugs with increased rates;
(c) whether some of the pharma companies do not adhere to the prescribed standards and norms for manufacturing, testing, labeling, packaging, storage and distribution of medicines;
(d) if so, whether there is any mechanism established by Government to monitor the rates of such pharma companies; and
(e) if so, the details of action taken by these mechanisms?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(MS. ANUPRIYA PATEL)

(a): As per the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), formulations listed in Schedule-I of the DPCO are defined as scheduled formulation under section 2(1)(zb) of DPCO, 2013. Formulations not included in Schedule –I are defined under Para 2(1)(v) of DPCO, 2013 as non-scheduled formulation. Thus, both schedule and non-schedule drugs are covered under DPCO, 2013.

(b): As per the extant provisions of DPCO, 2013, the ceiling prices of scheduled medicines are revised annually on the basis of Wholesale Price Index (WPI) (all commodities) for preceding calendar year by National Pharmaceutical Pricing Authority (NPPA), on or before 1st April of every year and is notified by the Government on the 1st day of April every year. The details of price fixed by NPPA are available at NPPA's website i.e. nppaindia.nic.in. In case of non-scheduled formulation (branded or generic), as per para 20 of DPCO, 2013, no manufacturers can increase Maximum Retail Price (MRP) by more than 10% of MRP during preceding 12 months. The maximum permissible increase in prices, as per the provisions of DPCO, 2013 for scheduled and non-scheduled drugs may or may not be availed by their respective manufacturers based on commercial considerations and market dynamics.

(c) to (e): Under the Drugs and Cosmetics Act, 1945 and Rules thereunder, manufacturers of drugs are required to comply with conditions of manufacturing licence and the requirements of

Good Manufacturing Practices (GMP). As per the Drugs Rules, 1945, the manufacturing, testing, labeling, packaging, storage and distribution are required to be carried out in compliance with the conditions of license including the Good manufacturing practices (GMP) prescribed under the Schedule M of the Drugs Rules, 1945. In case of violation, the Licensing Authority is empowered to take action as per the said Act and Rules.

NPPA monitors the prices of scheduled as well as non-scheduled medicines under DPCO, 2013. Action is taken against companies, found selling formulations at prices higher than the permissible price, and the overcharged amount is recovered from the company as per the relevant provisions of the DPCO, 2013. During the financial year 2023-24, Rs. 72.73 crore was recovered from the defaulting companies.

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