GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2221
TO BE ANSWERED ON THE 12th DECEMBER 2025

Optimization of Pharmaceutical Regulation

2221. Shri Tatkare Sunil Dattatrey:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the steps being taken by the Government to ensure efficient monitoring and evaluation regarding compliance with pharmaceutical rules and regulation in the country;
(b) the details of the data streams from the pharmaceutical sector (such as pricing, sales, prescription, research, etc.) that are combined and monitored by the Government; and
(c) whether there are any plans to set up a unified body dedicated to monitoring and analyzing data from the pharmaceutical sector to better guide policy making and intervention, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): The National Pharmaceuticals Pricing Policy, 2012 has the objective of putting in place a regulatory framework for pricing of drugs with a view to ensure availability of essential medicines at reasonable prices. The Drugs (Prices Control) Order, 2013 ("DPCO, 2013") has been issued based on the principles of NPPP, 2012 and is implemented by the National Pharmaceutical Pricing Authority (NPPA).

In accordance with the provisions of DPCO, 2013, NPPA fixes ceiling prices of scheduled formulations, *i.e.*, medicines included in the National List of Essential Medicines (NLEM) issued by the Ministry of Health and Family Welfare and incorporated in Schedule-I to DPCO, 2013. NPPA also fixes retail prices of new drugs as defined in DPCO, 2013. Further, in case of non-scheduled formulations, manufacturers are not permitted to increase the maximum retail price (MRP) of such formulations by more than 10% of MRP over a period of the preceding 12 months.

In addition, every manufacturer is required to issue a price list and supplementary price list in specified form to dealers, State Drugs Controllers and the Government, indicating reference to prices fixed or revised as aforesaid from time to time.

NPPA monitors compliance with DPCO, 2013 based on the references received from the Price Monitoring and Resource Units set up in States, State Drugs Controllers, NPPA's Pharma Sahi Daam app, samples purchased from the open market, reports from market database and complaints lodged through various grievance redress channels. Appropriate action is initiated

against drugs manufacturers for any violations after examination, in accordance with the provisions of DPCO, 2013.

Further, the Ministry of Health and Family Welfare has informed that regulatory control over manufacturing, sale and distribution of drugs is exercised through a system of licensing and inspection by State Licensing Authorities (SLAs) appointed by State Governments, while regulatory control over drugs imported into the country is exercised by the Central Government through the Central Drugs Standard Control Organisation (CDSCO). Drugs inspectors are required to inspect the facilities licensed under the Act from time to time, with a view to verify compliance with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder. Further, joint inspections of licensees are carried out by the drugs inspectors of CDSCO and States on a risk-based approach.

(b): NPPA utilises market-based data such as pricing, sales, quantity, moving average turnover etc. provided by third-party agency. It analyses and monitors the data to perform its core functions of fixation of ceiling/retail price, monitoring, overcharging assessment and overall market surveillance under DPCO, 2013.

(c): No such plan is currently under consideration.

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