

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA
STARRED QUESTION NO. *280
TO BE ANSWERED ON 29th March, 2022

Regulation of prices of non-scheduled drugs

280 Dr. L. Hanumanthaiah:

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

- (a) whether Government has decided to regulate prices of medicines or formulations not included in Schedule I of the Drugs (Prices Control) Order, 2013 (non-scheduled drugs) through the Trade Margin Rationalization (TMR) approach;
- (b) if so, whether the trade margin will be capped at the first point of sale; and
- (c) how the price at the first point of sale will be determined, whether on the actual price or a derived price based on a formula? ANSWER

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(DR. MANSUKH MANDAVIYA)**

(a) to (c): A statement is laid on the Table of the House.

Statement referred to in reply to Rajya Sabha Starred Question No. *280 for answer on 29.03.2022 by Dr. L. Hanumanthaiah regarding 'Regulation of prices of non-scheduled drugs'.

(a) to (c): As per extant provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013. A manufacturer is at liberty to fix the Maximum Retail Price (MRP) of non-scheduled drugs. NPPA monitors the prices of non-scheduled drugs so as to ensure that increase in their (MRP) is not more than 10% of what was prevalent during the preceding twelve months.

In the past, the NPPA by invoking the extraordinary powers under Para 19 of DPCO, 2013, in public interest, launched a Pilot on Trade Margin Rationalization (TMR) for 42 anti-cancer drugs vide order S.O. 1041(E) dated 27th February, 2019. Recently, NPPA also capped the trade margins of Oxygen Concentrators and five other medical devices viz., (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer vide order S.O. 2161(E) dated 3rd June 2021 and S.O. 2808 (E) dated 13th July 2021 respectively.

The methodology adopted by NPPA caps the trade margin at first point of sale, which is the price charged by the manufacturers to stockists/distributors/institutions, etc. Manufacturer(s) fix the MRP based on the formula given by NPPA using the price at first point of sale. The price at first point of sale, old MRP and revised MRP are reported by the manufacturer(s) to NPPA.
