

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

LOK SABHA
UNSTARRED QUESTION NO. 604
TO BE ANSWERED ON 09th December, 2022

Medicines added under National List of Essential Medicines

**604. SHRI THIRUNAVUKKARASAR SU:
SHRI P. RAVINDHRANATH:**

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

- (a) whether the Department of Pharmaceuticals has revised the National List of Essential Medicines and included several medicines under NLEM with price control;
- (b) whether the Government has constituted any monitoring mechanism to ensure the controlled price of such essential medicines, if so, the details thereof;
- (c) the number of medicines added so far under essential medicines - National List of Essential Medicines (NLEM);
- (d) whether the Government has recently added more drugs including four major anti-cancer drugs under the NLEM, if so, the details thereof;
- (e) whether some drugs were dropped from the NLEM and the steps taken/proposed to be taken to ensure affordable and quality medicines to all citizens in the country; and
- (f) if so, the details thereof and if not, the reasons therefor?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)**

(a): National List of Essential Medicines, 2022 (NLEM, 2022) was notified on 13.09.2022 by Ministry of Health and Family Welfare. Accordingly, Department of Pharmaceuticals (DoP) revised Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) vide S.O. 5249 (E) dated 11.11.2022. The National Pharmaceutical Pricing Authority (NPPA) under the DoP is mandated to fix the ceiling prices for the medicines included in revised schedule-I of DPCO 2013 within sixty days from the date of notification issued by the DoP.

(b): The NPPA under the DoP fixes the ceiling price for all scheduled drugs notified under Schedule-I of DPCO, 2013. No manufacturer of a scheduled formulation can sell a such formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, failing which such manufacturers shall be liable to deposit the overcharged amount along with interest thereon, from the date of such overcharging. A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation (branded or generic) launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum.

(c): NLEM 2022 consists of 388 medicines (including 2 animal vaccines and 2 stents for heart)

(d): A total of thirty-four (34) new medicines comprising of 4 anti-cancer drugs have been included in NLEM 2022. These are lenalidomide, leuprolide acetate, Irinotecan HCl Trihydrate and Bendamustine Hydrochloride.

(e) and (f): Twenty-six medicines have been dropped in NLEM 2022. NPPA is mandated to fix ceiling prices of the essential medicines contained in Schedule-I of DPCO, 2013 and monitors price trends so that drugs remain affordable to all citizens in the Country.
