

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

LOK SABHA
UNSTARRED QUESTION NO. 972
TO BE ANSWERED ON 3rd December, 2021

Affordability of Life Saving Drugs and Medical Machines

**972. SHRI SANGANNA AMARAPPA:
SHRI ANNASAHEB SHANKAR JOLLE:
SHRI L.S. TEJASVI SURYA:
SHRI B.Y. RAGHAVENDRA:
SHRI PRATHAP SIMHA:
SHRI Y. DEVENDRAPPA:
DR. UMESH G. JADHAV:**

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

- (a) whether the Government has taken any measures to increase the affordability of life-saving drugs and medical machines under the National Pharmaceutical Pricing Policy (NPPP); and
(b) if so, the details thereof?

ANSWER

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

(a) & (b): The objective of the National Pharmaceutical Pricing Policy (NPPP), 2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry. The key principles for regulation of prices as per the NPPP, 2012 are (i) Essentiality of Drugs, (ii) Control of Formulations prices only; and (iii) Market Based Pricing.

The Government has promulgated the Drugs (Prices Control) Order, 2013 (DPCO, 2013) based on provisions of NPPP, 2012. Accordingly, National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) fixes the ceiling prices of scheduled drugs listed in the National List of Essential Medicines (NLEM) and included as Schedule-I of the DPCO, 2013. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA.

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 provisions of 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.

The details of various medicines and medical devices under price control are as under:

- (i) Fixed ceiling prices of 882 scheduled formulations under Schedule-I of DPCO, 2013 including the ceiling prices of four scheduled medical devices, i.e., Hormone releasing IUD, IUD containing Copper, Bare metal stents and Drug Eluting Stents.
- (ii) Fixed retail price of 1,703 new drugs under DPCO, 2013.
- (iii) Fixed ceiling price of Orthopaedic Knee Implants under Para 19 of the DPCO, 2013 in public interest affecting price reduction up to 69%.
- (iv) Capped the Trade Margin of non-scheduled formulations of 42 Anti-cancer medicines under “Trade Margin Rationalization” approach as a Pilot for proof of concept, wherein price of more than 500 brands of medicines were reduced up to 90%.
- (v) Invoked Para 19 of the DPCO, 2013 to regulate the prices of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under “Trade Margin Rationalisation” Approach in June/July 2021.
