

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 3865
TO BE ANSWERED ON 11TH AUGUST, 2023**

PRICES OF ESSENTIAL DRUGS

3865: SHRI MOHAMMED FAIZAL P.P.:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details of the specific measures implemented by the Government to regulate the prices of essential drugs to ensure their accessibility to individuals facing challenges in affording them;
- (b) whether the Government has reduced the budget allocation for the Department of Health Research from Rs. 3200.65 crore in Budget Estimate (BE) 2022-23 to Rs. 2775 crore in Revised Estimate (RE) 2022-23;
- (c) if so, the details thereof and the reasons therefor; and
- (d) whether the Government has any plan to introduce a stricter price ceiling/cap on essential drugs/provide subsidies to drug manufacturers and industries with the aim of ensuring accessibility to middle and lower-income families in the country and if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) to (d): The Government has notified National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) with an objective to put in place a regulatory framework for pricing of drugs. The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are Essentiality of Drugs, Control of Formulations prices only and Market Based Pricing.

Drugs (Prices Control) Order, 2013 (DPCO, 2013) has been promulgated based on NPPP, 2012. Ministry of Health & Family Welfare publishes the National List of Essential Medicines (NLEM), which is incorporated as the Schedule-I of the Drugs (Price Control) Order. Formulations under Schedule-I are categorized according to their therapeutic category.

National Pharmaceutical Pricing Authority (NPPA) under the aegis of Department of Pharmaceuticals (DoP) fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). All manufacturers of scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. The annual increase/revision allowed in the case of Scheduled formulations is up to the level of annual revision, upward or downward, in Wholesale Price Index (WPI). The maximum permissible annual increase in the prices of Scheduled drugs may or may not be availed by the manufacturers. Decision by the manufacturers for increasing (within permissible limit) or decreasing the prices are based upon market dynamics.

As per information received from DoP, NPPA also fixes retail price of a new drug under DPCO, 2013 for existing manufacturers of scheduled formulation. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies. For other non-scheduled formulations, a manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation launched by it. In case of non-scheduled formulation, no manufacturer can increase Maximum Retail Price (MRP) by more than 10% of MRP during preceding 12 months. In addition, Para 19 of DPCO, 2013 provides for fixation of ceiling price or retail price of any drug in public interest for such period, as deemed fit, in case of extra-ordinary circumstances.

DoP notified Revised Schedule-I of DPCO, 2013 on 11.11.2022 based on National List of Essential Medicines (NLEM), 2022 notified by Ministry of Health & Family Welfare (MoH&FW) on 13.09.2022. Accordingly, NPPA has fixed ceiling prices of 691 formulations under NLEM 2022. The average reduction in ceiling price for 600 formulations (excluding 91 newly added formulations out of 691 formulations) due to price refixation under NLEM, 2022 works out to 16.71% compared with ceiling prices fixed under NLEM, 2015. This refixation of ceiling under NLEM 2022 resulted in net reduction of 6.73% after allowing WPI of 12.1218% with effect from 01.04.2023.

The details of drugs brought under price control/regulation by NPPA are given below:

- (i). Ceiling prices of 915 scheduled formulations have been notified as on 17.07.2023. Out of these, ceiling prices of 691 formulations have been fixed under NLEM, 2022 and for 224 formulations under NLEM, 2015.
- (ii). Retail price of around 2450 new drugs notified under DPCO, 2013 till 17.07.2023.
- (iii). In 2014, NPPA capped the MRP of 106 non-scheduled drug formulations under Para 19 of DPCO, 2013, which includes 22 diabetic and 84 cardiovascular drugs.
- (iv). Ceiling price of Orthopaedic Knee Implants fixed under Para 19 of DPCO, 2013 since 16th August 2017 in public interest.
- (v). Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines capped under "Trade Margin Rationalization" approach as a pilot for proof of concept, wherein price of about 500 brands of medicines were reduced upto 90%.

- (vi). NPPA invoked Para 19 of the DPCO, 2013 to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under "Trade Margin Rationalisation" approach in June/July 2021.

The details of prices fixed by NPPA are available on the website of NPPA i.e. nppaindia.nic.in.

The Revised Estimate (RE) of Rs. 2775 crore allocated to Department of Health Research is due to underutilisation in Prime Minister's Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) scheme which is due to steep fall in prices of testing kits, testing equipment/machines, re-agents, etc. as a result of indigenous production and also decentralization of COVID-19 related procurement to the States/UTs. The other reasons for non-usage of allocated funds is complex nature of tendering process for establishment of Biological Safety Level (BSL) III and BSL IV labs and Regional Research Platform for WHO South East Asia Region which involves co-ordination and Memorandum of Understandings with south East Asian countries.
