GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION NO. †1945 TO BE ANSWERED ON 02nd August, 2024

Prices of Essential Drugs

†1945 Shri Ram Shiromani Verma:

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

- (a) the criteria/guidelines prescribed by the Government/National Pharmaceutical Pricing Authority for determining and deciding prices of essential drugs including drugs used for treatment of cancer, diabetes, HIV, heart and kidney diseases;
- (b) whether the prices of essential drugs and other drugs have increased many fold;
- (c) if so, the details thereof and the reasons therefor; and
- (d) the steps taken/proposed to be taken by the Government to control/reduce the prices of pharmaceuticals/drugs during each of the last three years and the current year and the extent to which success has been achieved in this regard?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (d): National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals (DoP) regulates the prices of drugs as per National Pharmaceuticals Pricing Policy, 2012 and provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013). The key principles of the policy are Essentiality of Drugs, Control of Formulations Pricing and Market Based Pricing. The National List of Essential Medicines (NLEM) of the Ministry of Health & Family Welfare (MHFW) is incorporated as Schedule-I of the DPCO, 2013. Medicines under NLEM, 2022 are mentioned according to their therapeutic category. Anti-cancer formulations including immunosuppressive and palliative care are mentioned under Section 7, Anti-diabetic medicines under Section 18.3.1, Medicines used in HIV under Section 6.7, Cardiovascular Medicines under Section 10, and Diuretics are mentioned under Section 15 of Schedule-I of DPCO, 2013.

NPPA fixes ceiling prices of scheduled medicines specified in Schedule-I of the DPCO, 2013 in accordance with the provisions of 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.

Ceiling prices of 926 scheduled formulations across various therapeutic categories are effective as on 29.07.2024. These includes 131 anti-cancer, 11 anti-diabetes, 29 anti-HIV, 65 cardio vascular, 1 haemodialysis solution and 10 Diuretics scheduled formulations.

Further the retail price of a new drug as defined in para 2(1)(u) of DPCO, 2013 are fixed by NPPA as per Para 5 of DPCO, 2013 for existing manufacturers of scheduled formulations. The retail price of a new drug is applicable to the applicant manufacturer and marketer and they cannot sell the new drug above the price notified by NPPA. Upto 29.07.2024, retail price of around 2,894 new drugs have been notified under DPCO, 2013 including drugs used for treatment of cancer, diabetes, HIV, heart and kidney diseases.

In case of non-scheduled formulation, 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, 2013 the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum in the preceding 12 months. Instances of overcharging are dealt with by NPPA under the relevant provisions of the DPCO, 2013.

As per provisions of DPCO, 2013, the ceiling prices of scheduled medicines are revised annually on the basis of Wholesale Price Index (WPI) (all commodities) for the preceding calendar year on or before 1st April of every year, which is notified by the Government on the 1st day of April every year.

The WPI increase is based on the data published by Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India. For the Financial year 2024-25, the annual change in WPI of all commodities worked out as 0.00551% during the calendar year 2023 over the corresponding period in 2022. Accordingly, the ceiling prices of the formulations have been increased by 0.00551% w.e.f. 01.04.2024. Although, the annual permitted increase in the prices of Scheduled drugs is based on the increase in WPI (all commodities), the WPI increase is the maximum permissible increase which may or may not be availed of by the manufacturers based on market dynamics.

NELM, 2022 was notified on 11.11.2022 as Schedule-I of DPCO, 2013. The fixation of ceiling price of scheduled formulation under NLEM, 2022 has resulted in average reduction of 16.82% in the prevailing prices.
