GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 728
TO BE ANSWERED ON 7th FEBRUARY, 2025

Prices of Branded Drugs

728. Ms Sayani Ghosh:

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

(a) whether the Government is considering regulating the prices of branded drugs as recommended by experts, if so, the details thereof;
(b) whether the Government is providing any incentives to pharmaceutical companies to develop and manufacture orphan drugs for rare and neglected diseases, if so, the details thereof; and
(c) whether the Government has taken note of the apprehensions of medical practitioners regarding the efficacy and safety of generic medicines, given that branded drugs have become unaffordable for the public, if so, the steps taken in this regard?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): The Department of Health and Family Welfare notifies the National List of Essential Medicines (NLEM), based on the report of the Standing National Committee on Medicines. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes ceiling prices under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013) in respect of the medicines included in NLEM, which are specified in Schedule-I to DPCO, 2013. Manufacturers of scheduled medicines (both branded and generic) are required to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by NPPA. In addition, NPPA fixes the retail price of new drugs as defined in DPCO, 2013. The retail price of a new drug is applicable to the applicant manufacturer and marketer, who are required to sell the new drug within the price notified by NPPA. In case of non-scheduled formulations, a manufacturer is at liberty to fix the maximum retail price (MRP) of drugs launched by it. However, as per DPCO, 2013, a manufacturer is required to not increase MRP of a non-scheduled drug by more than 10% of MRP during the preceding 12 months. In addition to the above, the ceiling price of a drug may also be fixed under certain circumstances, in public interest. All price notifications for the formulations whose prices have been fixed by NPPA are available on its website (www.nppaindia.nic.in).

(b): With the objective of enhancing India's manufacturing capabilities by increasing investment and production in the pharmaceutical sector, the Department of Pharmaceuticals is implementing the Production Linked Incentive (PLI) Scheme for Pharmaceuticals to provide financial incentive for manufacturing product under identified product categories, which include orphan drugs. Under the scheme, eight orphan drugs for treatment of rare diseases have been approved.

Further, under the Scheme for Promotion of Research and Innovation in the Pharma MedTech Sector, launched by the Department of Pharmaceuticals, provision exists for extending financial assistance to industries, MSMEs and startups for investing in research and development in identified priority areas, which include orphan drugs.

Moreover, DPCO, 2013 provides for exemption from its provisions for drugs used for treating orphan diseases as decided by the Ministry of Health and Family Welfare.

(c): The standards of quality and safety specified under the Drugs and Cosmetics Act, 1940 apply equally to all drugs manufactured in the country, irrespective of whether they are generic or branded. As and when any complaints are received, the matter is referred to State Licensing Authorities, which are empowered to take action in respect of violations, for taking action as per the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945.

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