GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 5720
TO BE ANSWERED ON 4th APRIL, 2025

Price Regulation of Combination Drugs

5720. Dr. Amol Ramsing Kolhe:
Shri Nilesh Dnyandev Lanke:
Prof. Varsha Eknath Gaikwad:
Shri Bhaskar Murlidhar Bhagare:
Smt. Supriya Sule:
Shri Mohite Patil Dhairyasheel Rajsinh:
Shri Sanjay Dina Patil:

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

(a) whether the Government pharmaceutical companies use combination drugs as a strategy to control pricing and extend patents, if so, the details of such cases identified during the last five years;
(b) whether use of combination drugs by pharmaceutical companies limits competition in the market, if so, the measures taken by the Government to prevent anti-competitive practices in the pharmaceutical industry;
(c) the role of the Government and regulatory bodies in ensuring that combination drugs remain affordable for consumers;
(d) whether there are specific price control measures applied to combination drugs under the National Pharmaceutical Pricing Authority (NPPA), if so, the number of combination drugs that have been approved and price-capped under NPPA regulations in the last five years; and
(e) whether the Government faces regulatory challenges in monitoring and approving combination drugs, if so, the steps being taken to strengthen regulatory oversight to prevent the misuse of combination drugs?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (e): As per information received from the Ministry of Health and Family Welfare (MoHFW), the manufacture, sale and distribution of drugs in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder, through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by State Licensing Authorities (SLAs) appointed by the State Governments concerned. As per rule 2(w)(iii) of the New Drugs and Clinical Trials Rules, 2019, fixed dose combinations (FDCs) of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved

combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form, come under the definition of "new drug". For the manufacture of any FDC falling under the definition of new drug, permission is required from the Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing licence for the new drug from the SLA concerned. On receipt of application for approval of such a new drug, the same is examined for safety and efficacy, in consultation with the Subject Expert Committee concerned, and decisions are taken based on the recommendations of the committee and fulfilment of requirements under the rules.

MoHFW notifies the National List of Essential Medicines (NLEM), which is incorporated as the Schedule-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling prices of these scheduled medicines, including combination drugs listed therein, in accordance with the provisions of DPCO, 2013. All manufactures and marketers of scheduled medicines are required to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by NPPA.

NPPA also fixes retail prices of new drugs, as defined in DPCO, 2013, which refers to a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in NLEM by combining the drug with another drug either listed or not listed in NLEM or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in NLEM. The retail price of a new drug is applicable to the applicant manufacturer and marketer, who are required to sell their products within the price notified by NPPA.

For non-scheduled formulations, including formulations of combination drugs, manufacturers may not increase the maximum retail price by more than 10% per annum.

As on 1.4.2024, ceiling prices of 928 formulations were in effect and retail prices of over 3,200 new drugs, including combination drugs, stood fixed by NPPA, including over 2,000 retail prices fixed in the last five years. Details of prices fixed by NPPA are available on its website (www.nppaindia.nic.in).

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