

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

LOK SABHA
UNSTARRED QUESTION NO. †55
TO BE ANSWERED ON 2nd February, 2024

Price Fixation of Medicines

†55. **SHRI ANIL FIROJIYA:**

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

- (a) the standards set for fixing the prices of medicines in the country; and
- (b) the names of the countries with which India has signed an agreement for regulation and enhancement of the quality of medicinal products in the country?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)**

(a): National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) lays down the principles for regulation of prices of drugs. The key principles of the policy are the essentiality of drugs, control of formulation prices only and market-based pricing. Based on NPPP, 2012, the Drug Prices Control Order, 2013, (DPCO, 2013) has been issued under section 3 of the Essential Commodities Act, 1955. The National List of Essential Medicines (NLEM) is issued by the Ministry of Health & Family Welfare (MHFW) from time to time. The NLEM as notified by MHFW is incorporated in the Schedule-I of DPCO, 2013 which constitutes the list of scheduled medicines for price control.

National Pharmaceutical Pricing Authority (NPPA) under the aegis of the Department of Pharmaceuticals (DoP) fixes the ceiling price of medicines specified in Schedule-I of the 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. NPPA also fixes the retail prices of new drugs as defined in DPCO, 2013 for existing manufacturers of scheduled formulations. For Non-Scheduled Formulations (branded or generic), the manufacturers are at liberty to fix the maximum retail price of the formulation launched by it, however, they may not increase the maximum retail price of such formulations by more than 10% per annum. Further, the Government may also fix the ceiling price or retail price of any drug in the public interest, under extra-ordinary circumstances, for such period as it may deem fit.

(b): As per the information provided by MHFW, the Central Drugs Standard Control Organisation (CDSCO) has signed bilateral agreements such as Memorandum of Understanding (MoU), Memorandum of Co-operation (MOC), Joint Declaration of Intent (JDI) and Memorandum of Intent (MoI) with Drug Regulatory Authorities of 14 countries for

co-operation in the field of regulation of medicinal products. CDSCO has signed bilateral agreements with its counterparts of the following countries:

1. Afghanistan
2. Argentina
3. Brazil
4. Dominican Republic
5. Ecuador
6. Germany
7. Japan
8. Russia
9. Saudi Arabia
10. Sweden
11. Suriname
12. United Kingdom
13. USA
14. The Netherlands
