

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

RAJYA SABHA
UNSTARRED QUESTION NO. 180
TO BE ANSWERED ON 04th FEBRUARY, 2025

Principles for price regulation of drugs

180 Dr. Dharmasthala Veerendra Heggade:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) the details of the policy that lays down the principles for regulation of prices of drugs in the country; and
- (b) the names of the countries with which India has signed bilateral agreement for regulation of the quality of medicinal products in the country?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): The National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) lays down the regulatory framework for pricing of drugs. The key principles for regulation of prices in the said policy are (i) regulation on the basis of essentiality of drugs, (ii) regulation of prices of formulations only, *i.e.*, medicines used by consumers and not the upstream products such as bulk drugs or intermediates, and (iii) regulation through market-based pricing as against cost-based pricing under the Drugs (Prices Control) Order, 1995. The details of the policy are available in the Gazette notification dated 7th December 2012 of the Department of Pharmaceuticals [[https://egazette.gov.in/\(S\(cjt0i1uouyc1bl3ozo3jx3qk\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(cjt0i1uouyc1bl3ozo3jx3qk))/ViewPDF.aspx)].

(b): As per the information provided by the Department of Health and Family Welfare, the Central Drugs Standard Control Organisation has signed agreements or memorandum of understandings on regulatory cooperation with other international agencies, including with such agencies in Afghanistan, Argentina, Brazil, Denmark, Dominican Republic, Ecuador, Germany, Guyana, Japan, Netherlands, Russian Federation, Suriname, Sweden, Ukraine, United Kingdom and United States of America and the Drug Regulatory Authority of BRICS.
