GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 991
TO BE ANSWERED ON THE 9th DECEMBER, 2025

Quality and pricing of medicines

991 Dr. Medha Vishram Kulkarni:

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

(a) whether Government has taken note that the production cost of several essential medicines is much lower than their market selling price;
(b) the steps taken by Government to ensure affordable pricing of medicines for the common public;
(c) the number of medicines brought under the Drug Price Control Order (DPCO) in the last three years; and
(d) whether any mechanism has been developed to ensure quality assurance and prevent overpricing by private pharmaceutical companies?

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 principles for regulation of prices of drugs. The key principles for regulating the prices under NPPP, 2012, *inter alia*, include regulating the prices of formulations through market-based pricing as against cost-based. This policy is effected through the extant Drugs (Prices Control) Order, 2013 ("DPCO, 2013"), under which price fixation is based on widely available information in the public domain, as against individual manufacturer's costing data.

(b) and (c): The National Pharmaceutical Pricing Authority (NPPA) fixes ceiling prices of medicines included in the National List of Essential Medicines (NLEM) issued by the Ministry of Health and Family Welfare and incorporated in Schedule-I to DPCO, 2013. All manufacturers, marketers and importers of scheduled medicines are required to sell their products within such ceiling price (plus applicable local taxes).

NPPA also fixes retail prices of new drugs as defined in DPCO, 2013, *i.e.*, formulations launched by existing manufacturers of a medicine listed in NLEM by combining it with another drug, or by changing the strength or dosage or both of such medicine. The applicant manufacturer is required to not sell the new drug above the price fixed by NPPA.

Further, in case of non-scheduled formulations, manufacturers are not permitted to increase the maximum retail price (MRP) of such formulations by more than 10% of their MRP over a

period of the preceding 12 months. In addition, the NPPA has taken measures to regulate the prices of drugs in extraordinary circumstances in public interest.

The details of drugs brought under price control/regulation by NPPA under DPCO, 2013 to ensure reasonable pricing of medicines for the common public are given below:

(i) Ceiling prices stand fixed for 935 scheduled formulations as on 1.12.2025. Average price reduction due to refixation of prices under the NLEM, 2022 was about 17%, leading to annual total savings of around ₹3,802 crore to public.

(ii) Retail price of more than 3,600 new drugs under DPCO, 2013 have been notified till 1.12.2025.

(iii) In 2014, NPPA capped MRP of 106 non-scheduled anti-diabetic and cardiovascular treatment drugs, resulting in estimated annual savings of about ₹350 crore to patients.

(iv) Trade margin of non-scheduled formulations of 42 select anti-cancer medicines were capped under a trade margin rationalisation approach, wherein price of about 500 brands of medicines were reduced by an average of about 50%, resulting into estimated annual saving of about ₹ 984 crore to patients.

(v) In February 2017, ceiling prices of coronary stents were fixed, resulting in estimated annual savings of about ₹11,600 crore to patients.

(vi) In August 2017, ceiling prices of orthopaedic knee implants were fixed, resulting in estimated annual savings of about ₹1,500 crore to patients.

(vii) In June/July 2021, trade margin of oxygen concentrators, pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer were also capped, resulting in estimated annual savings of about ₹1,000 crore to consumers.

Details of prices fixed or revised by NPPA are available on NPPA's website (www.nppa.gov.in). These and other measures taken have together helped in ensuring annual savings of up to ₹25,000 crore and India's drug prices being generally the lowest in the world. In addition, Government has taken other measures to improve the access of essential medicines at affordable rates to the common man which include the following:

(i) The Government has launched the Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme under which quality generic medicines is provided through more than 17,000 Janaushadhi Kendras at rates that are typically 50% to 80% cheaper than branded medicines.

(ii) Under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) of the Department of Health and Family Welfare, health assurance/insurance cover of ₹5 lakh per family per year is provided for secondary or tertiary care hospitalisation, including for medicines. Over 42 crore persons have been issued PMJAY cards.

(iii) Under the Free Drugs Service Initiative of the National Health Mission, essential medicines list recommended under the Indian Public Health Standards (IPHS) are made available free of any charge at public health facilities ranging from Primary Health Centres (PHCs) to district hospitals across the country.

(iv) Under the Amrit (Affordable Medicines and Reliable Implants for Treatment) initiative of the Department of Health and Family Welfare, affordable medicines are provided for the treatment of cancer, cardiovascular and other diseases, implants, surgical disposables and other consumables etc., at an average discount of up to 50% on market rates through AMRIT Pharmacy stores set up in number of hospitals and healthcare institutions.

(v) Financial assistance is provided to poor patients belonging to families living below the poverty line, who suffer from major life-threatening diseases including cancer, under the umbrella scheme of Rashtriya Arogya Nidhi and the Health Minister's Discretionary Grant.

(d): With regard to prevention of overpricing and the mechanism therefor, it is informed that DPCO, 2013 requires every manufacturer of a formulation to print the maximum retail price on the label of the container of such formulation. Further, no person is permitted to sell any formulation to any consumer at a price exceeding the price specified on the current price list or price indicated on the label of the container or the pack thereof, whichever is less. Moreover, NPPA monitors the prices of both scheduled and non-scheduled formulations on an ongoing basis and takes action in accordance with the provisions of DPCO, 2013 against companies that are found as overcharging consumers, based on references received regarding overcharging from any source, including Price Monitoring and Resource Units set up in States, State Drugs Controllers, samples purchased from open market, reports from market database and complaints lodged through various grievance redress channels.

As regards quality assurance, as per information furnished by the Ministry of Health and Family Welfare, the following measures have been taken to ensure quality of medicines produced across the country:

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organisation (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 960 premises since December 2022 and based on findings, more than 860 actions such as issuance of show cause notices, stop production order, suspension, cancellation of licenses/product-licenses, warning letters etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules, 1945.

(ii) The Drugs Rules, 1945 have been amended in 2023 to require manufacturers of the top-300 drug formulation brands listed in Schedule H2 to the said rules to print or affix a bar code or QR code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the said rules have also been amended to require that every active pharmaceutical ingredient (bulk drug), whether manufactured or imported, shall bear a QR code on each level of packaging containing data readable through software applications to facilitate tracking and tracing.

(iii) As part of quality monitoring, CDSCO uploads details of drug samples that fail quality checks on its website as monthly drug alerts. For samples declared Not of Standard Quality (NSQ) by the drugs testing laboratories under CDSCO, manufacturers are directed to immediately recall the product and stop further distribution. Based on investigation findings, licensing authorities concerned take action under the Drugs and Cosmetics Act, 1940 and the rules made thereunder, including stop-production/testing orders, license suspension or cancellation, warning letters and show cause notices.

(iv) Schedule M to the Drugs Rules, 1945 has been revised *vide* Ministry of Health and Family Welfare's notification dated 28.12.2023, in line with international standards {of the World Health Organization (WHO)}, and the same has come into effect for drug manufacturers with turnover more than ₹250 crore from 29.6.2024. However, for manufacturers having turnover of up to ₹250 crore, the timeline for

implementation has been extended till 31.12.2025, *vide* notification dated 11.2.2025.

(v) In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics and medical devices by Central and State drugs inspectors. These provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.

(vi) An online portal, SUGAM, is in place since September 2023 for integrating the drug testing labs of CDSCO. It automates the entire workflow for testing of medical products (drugs, vaccine, cosmetics and medical devices) to meet quality specifications and trace testing status in laboratories.

(vii) The Drugs Rules, 1945 have been amended to make it mandatory that, in case an applicant intends to market the drug under a brand name or trade name, such applicant shall furnish an undertaking in prescribed form to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

(viii) For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central drugs regulator coordinates activities of the State Drugs Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

(ix) Central Government organises residential and regional training and workshops on an ongoing basis to officials of CDSCO and State Drugs Regulatory Authorities on Good Manufacturing Practices. Since April 2023, CDSCO has trained over 43,000 persons.

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