

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

LOK SABHA
STARRED QUESTION No. 292
TO BE ANSWERED ON THE 5th AUGUST, 2022

Anomalies in Prices of Medicines

***292. DR. HEENA GAVIT:
DR. KRISHNA PAL SINGH YADAV:**

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

- (a) whether the Government has taken/proposes to take any concrete measures to facilitate the pharma sector in the country and if so, the details thereof, State/ UT-wise including the State of Uttar Pradesh;
- (b) whether the Government has taken serious note of the anomalies in prices as well as quality of certain medicines marketed by different pharma companies under different brand names and if so, the details thereof;
- (c) the details of the total quantity and value of drugs/medicines imported and exported during the last three years; and
- (d) the details of the steps taken by the Government to reduce the dependence on imported drugs and increase the indigenous production in the country?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(DR. MANSUKH MANDAVIYA)**

(a) to (d): A statement is laid on the Table of the House.

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STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (d) OF STARRED QUESTION NO. 292 FOR REPLY ON 05.08.2022

(a) & (d): The Government of India has taken several measures to encourage domestic manufacturing of Pharmaceutical drugs including bulk drugs to reduce import dependence and to establish a dominant position in the global market. The Programmatic interventions to support Pharma Industries are as follows;

- (i) The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. A total of 51 applicants have been selected under the scheme.
- (ii) The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years.
- (iii) The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks. The proposals received are under evaluation.
- (iv) The Department has launched the scheme of Strengthening of Pharmaceutical Industry (SPI), with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26 and this scheme has three components, to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs. Applications are invited under the scheme components (Assistance to Pharmaceutical Industry for Common Facilities (API-CF) from eligible clusters and Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) from eligible MSME units) since 1.8.2022.

Further, under non-schematic interventions, in order to attract investments in this sector, the Government has allowed 100% FDI in pharma sector for greenfield projects under automatic route. For the brownfield projects, upto 74%, FDI investments are allowed under automatic route and beyond 74% to 100%, FDI investments are allowed under government approval route.

(b): As per the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), the ceiling price of scheduled formulations as per Schedule-I of DPCO, 2013 based on the National List of Essential Medicines (NLEM) is fixed by the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals. All manufacturers of scheduled medicines are required to sell their products within the ceiling price (plus applicable taxes) fixed by the NPPA. NPPA also fixes retail price of a new drug under DPCO, 2013 for existing manufacturers of scheduled formulation.

In respect of non-scheduled formulations, a manufacturer is at liberty to fix its Maximum Retail Price (MRP). However, a manufacturer of a non-scheduled formulation (including new drug) cannot increase the price by more than 10% of what was prevalent during the preceding 12 months.

Annual revision of ceiling prices of scheduled medicines is permissible based on Wholesale Price Index (WPI) for all commodities for the preceding calendar year.

Further, 10% increase in MRP in case of non-scheduled drugs and WPI increase in case of scheduled drugs is the maximum increase permissible, which may or may not be availed by the manufacturers. The manufacturers decide the market price based on market dynamics, within the ceiling or retail price, wherever prescribed, by NPPA.

In view of this, though the prices are regulated under DPCO, 2013, the prices for medicines may vary among different pharma companies as far as there is no violation of prices fixed by NPPA and the prices are increased within the prescribed limits.

Action taken so far under by NPPA are given below:

- i. Ceiling prices of 890 scheduled formulations across various therapeutic categories including scheduled medical devices, i.e., Intra Uterine Devices (Hormone releasing IUD & IUD containing Copper), condoms and coronary stents (Bare metal stents and Drug Eluting Stents) have been fixed by NPPA.
- ii. Retail price of approx. 2023 new drugs under DPCO, 2013 till 12.07.2022 have been fixed.
- iii. In 2014, NPPA capped the MRP of 106 non-scheduled drug formulations under Para 19 of DPCO 2013 which includes 22 diabetic and 84 cardiovascular drugs.
- iv. Ceiling price of Orthopaedic Knee Implants fixed under Para 19 of DPCO, 2013 in August 2017 in public interest.
- v. Capped Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines as a pilot for proof of concept wherein price of above 500 brands of medicines were reduced upto 90%.
- vi. Paragraph 19 of the DPCO, 2013 was invoked to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under "Trade Margin Rationalization" Approach in June/July 2021.

As per the information received from Central Drugs Standard Control Organisation (CDSCO), CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country. Major such reforms are as under: -

- i. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act, 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
- ii. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts.
- iii. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 478 till January 2022 and 220 posts have recently been created on 27-06-2022.
- iv. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.
- v. On 3.4.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.
- vi. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of

manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk-based approach.

- vii. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.
- viii. Draft Rules have been published vide GSR 999 (E), dated 05.10.2018 to amend the Schedule-M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive at par with the WHO-GMP guidelines.
- ix. The Government had approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs.1750 crores. Out of this, Rs. 900 crore was for strengthening the central drug regulatory structures and Rs.850 crore was for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore was released under the Central component whereas Rs. 87.90 crore was allocated during 2018-19 under this component. Rs. 82.90 crore was allocated during the year 2019-20. Under the State component, Rs. 81.36 crore was released during 2016-17 and 17-18 whereas Rs. 206 crore was allocated during 2018-19 under this component.

(c): The quantity and the value of the drugs exported and imported during the last three years is as under: -

Export and Import of Drugs and Pharmaceuticals				
Year	Export		Import	
	Quantity (MT)	Value (In Rs Cr)	Quantity (MT)	Value (In Rs Cr)
2019-20	524757	1,40,537	386186	40,139
2020-21	642718	1,74,064	403878	46,808
2021-22	1075906	1,75,040	423966	60,060

Source: DGCIS, Ministry of Commerce and Industry.