GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO.186
TO BE ANSWERED ON THE 2nd DECEMBER, 2025

PLI for pharmaceutical and medical devices

186 Shri Iranna Kadadi:

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

(a) the current status of the Production Linked Incentive (PLI) scheme for pharmaceuticals and its impact on domestic manufacturing;
(b) the progress of the PLI scheme for promoting domestic manufacturing of medical devices;
(c) the steps being taken to ensure the affordability and availability of essential medicines under the NPPA;
(d) the status of the establishment of the three bulk drug parks and four medical device parks; and
(e) the manner in which the Ministry is regulating online pharmacies and the sale of medicines?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): Details regarding the current status of the PLI schemes for pharmaceuticals and their impact on domestic manufacturing are as under:

(i) *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 (also known as PLI scheme for Bulk Drugs):* The scheme is aimed at avoiding disruption in supply of critical APIs used to make critical drugs for which there are no alternatives by reducing supply disruption risk due to excessive dependence on single source. The scheme has a budgetary outlay of ₹6,940 crore. Till September 2025, investment of ₹4,763.34 crore has already been made in three and a half years of scheme production period, against an investment commitment of ₹4,329.95 crore over the period of six years in greenfield projects. Further, production capacities have been created for 26 KSMs/DIs/APIs, which were earlier primarily imported. The scheme has resulted in cumulative sales of ₹2,315.44 crore reported till September 2025,

including exports of ₹508.12 crore, thereby avoiding imports worth ₹1,807.32 crore.

(ii) *PLI Scheme for Pharmaceuticals*: The scheme is aimed at enhancing India's manufacturing capabilities by increasing investment and production in the pharmaceuticals sector and contributing to product diversification to high-value goods in the pharmaceutical sector and incentivises production of high-value medicines such as biopharmaceuticals, complex generic drugs, patented drugs or drugs nearing patent expiry, auto-immune drugs, anti-cancer drugs, etc. as well as production of APIs/DIs/KSMs other than those notified under the PLI Scheme for Bulk Drugs. It has a budgetary outlay of ₹15,000 crore. As of September 2025, the committed investment of ₹17,275 crore targeted over the six-year period of the scheme stands substantially exceeded with cumulative investment of ₹40,890 crore made in three and a half years of scheme production period in both brownfield and greenfield projects. Further, 726 APIs/KSMs/DIs are being manufactured under the scheme, including 191 which have been manufactured for the first time under the scheme. Cumulative domestic sales of APIs/KSMs/DIs produced under the scheme till September 2025 is worth ₹26,123 crore and thereby contributing to import avoidance.

(b): The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices has a budgetary outlay of ₹3,420 crore and a five-year performance-linked incentive period from FY2022-23 to FY2026-27. Under the scheme, selected companies are eligible for financial incentive for incremental sales of domestically manufactured medical devices in the radiotherapy, imaging device, anaesthesia, cardio-respiratory and critical care and implant device segments, for a period of five years. As of September 2025, 22 greenfield projects have been commissioned and production has started for 55 products, which include high-end medical devices on which the country has been highly import-dependent, such as linear accelerators, machines for MRI and CT scans and mammograms, C-arm X-ray machines, MRI coils and ultrasound machines. Till September 2025, cumulative eligible sales of ₹12,344.37 crore have been made under the scheme, including export sales worth ₹5,869.36 crore.

(c): The National Pharmaceutical Pricing Authority (NPPA) fixes ceiling prices of medicines included in the National List of Essential Medicines issued by the Department of Health and Family Welfare, which is included in Schedule-I to the Drugs (Prices Control) Order, 2013 ("DPCO, 2013"). All manufacturers, marketers and importers of such scheduled medicines are required to sell their products within the ceiling price (plus applicable local taxes). As on 26.11.2025, ceiling prices of 935 scheduled formulations have been fixed by NPPA.

In addition, retail prices of "new drugs", *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, are also fixed by NPPA under DPCO, 2013. Retail prices of over 3,500 such new drugs also stand fixed, and applicant manufacturers and marketing companies are required to sell these drugs within the said price. Further, manufacturers, marketers and importers are required to not increase the

maximum retail price (MRP) of drugs launched by them by more than 10% during the preceding 12 months. In addition, NPPA has fixed prices of number of non-scheduled medicines, under an exceptional provision of DPCO, 2013, in public interest, as follows:

(i) MRP of 22 diabetic and 84 cardiovascular non-scheduled medicines has been capped, resulting in estimated annual savings of about ₹350 crore to patients.
(ii) Trade margin of 42 non-scheduled anti-cancer medicines have been capped, resulting in reduction in prices of about 526 brands of medicines by an average of about 50%, resulting in estimated annual savings of about ₹ 984 crore to patients.
(iii) Ceiling prices of orthopaedic knee implants have been fixed, resulting in estimated annual savings of about ₹1,500 crore to patients.
(iv) The trade margins of oxygen concentrators, pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer were capped in June/July 2021, resulting in estimated annual savings of about ₹1,000 crore to consumers.

The details of prices fixed by NPPA are available on the website of NPPA, *i.e.*, nppaindia.nic.in. In cases of overcharging in sale of medicine, NPPA initiates action against the companies concerned in accordance with the provisions of DPCO, 2013.

NPPA monitors the availability of medicines and responds to any shortages reported by directing companies to supply stocks to the places of reported shortage, increase production and submit detailed production and sales data to assess supply gaps.

(d): Under the scheme for Promotion of Bulk Drug Parks, with a budgetary outlay of ₹3,000 crore, under which three bulk drug parks have been approved and are at various stages of development in the States of Andhra Pradesh, Gujarat and Himachal Pradesh, through their respective State implementing agencies. The total project cost of these parks is over ₹6,306.68 crore, with Central assistance to the tune of ₹1,000 crore each for creation of common infrastructure facilities. These parks envisage land and utilities such as power, water, effluent treatment plant, steam, solid waste management and warehouse facilities at a subsidised rate to bulk drug or API manufacturers for units set up in the park. The State implementing agencies of the States concerned have also offered fiscal incentives in the form of capital subsidy on fixed capital investment, interest subsidy, State Goods and Services Tax reimbursement, exemption of stamp duty and registration charges, etc. Further, the scheme provides for applicants for allotment of land in the parks to set up units for manufacturing products prioritised in the PLI Scheme for Bulk Drugs to have priority in land allotment.

Under the scheme for Promotion of Medical Device Parks, three parks have been approved and are at an advanced stage of development in Greater Noida (Uttar Pradesh), Ujjain (Madhya Pradesh) and Kanchipuram (Tamil Nadu) districts. The total project cost of these is ₹871.11 crore, with Central assistance to the tune of ₹100 crore each for creation of common infrastructure facilities, which is expected to enhance industry's competitiveness and reduce production costs through optimisation of resources and

economies of scale. As of November 2025, out of a total of ₹300 crore for the three parks, a total of ₹180 crore stood released. Civil construction for the three parks is at the final stages. As of September 2025, 194 medical devices manufacturers have been allotted land in the three parks in a 298.58 acre area and 34 units have commenced construction of their plants.

The manner in which the Ministry is regulating online pharmacies and the sale of medicines

(e): Regulation of pharmacies and sale of medicines is governed by the provisions of Drugs and Cosmetics Act, 1940, which is administered by the Department of Health and Family Welfare. The said Department has informed that the sale and distribution of drugs are regulated by State Licensing Authorities appointed by the State Government concerned under the said Act and the rules made thereunder. These authorities are empowered under the said Act and rules for implementing and monitoring compliance with the same and, in case of non-compliance, to take action in accordance with the provisions of the Act and rules.

The Department has further informed that, with a view to comprehensively regulate online sale of medicines, Government of India published draft rules *vide* notification dated 28.8.2018, inviting comments from public/stakeholders for amendments to the Drugs Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacies. The said draft rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedures for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e-pharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.

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