GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA UNSTARRED QUESTION NO.186 TO BE ANSWERED ON 22nd July, 2025

Atmanirbhar Bharat in Pharmaceuticals

186 Shri Sadanand Mhalu Shet Tanavade:

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

- (a) the key steps taken by Government to promote Atmanirbhar Bharat in the pharmaceutical sector, particularly in the areas of Active Pharmaceutical Ingredients (APIs), bulk drugs, and medical devices;
- (b) the manner in which Government is supporting domestic research, innovation, and technology development to reduce reliance on pharmaceutical imports;
- (c) the progress made under schemes like the Production Linked Incentive (PLI) Scheme and Bulk Drug Parks Scheme, along with their budgetary allocations and their impact on India's global pharmaceutical leadership;
- (d) the contribution of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana in improving access to affordable medicines; and
- (e) whether a National Pharmaceutical Innovation Mission is being considered, and if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SMT. ANUPRIYA PATEL)

- (a) to (c): Number of schemes are being implemented to realise the vision of Atmanirbhar Bharat in the pharmaceutical sector and to support domestic innovation and reduce reliance on pharmaceutical imports, including the following:
 - (i) Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme;
 - (ii) Production Linked Incentive (PLI) Scheme for Pharmaceuticals;
 - (iii) PLI Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India (also known as the PLI Scheme for Bulk Drugs);
 - (iv) Bulk Drug Parks Scheme;
 - (v) Strengthening of Pharmaceutical Industry scheme;
 - (vi) PLI Scheme for Promoting Domestic Manufacturing of Medical Devices;
 - (vii) Scheme for Promotion of Medical Devices Parks; and
 - (viii) Scheme for Strengthening Medical Device Industry.

The PRIP scheme has been launched with an outlay of ₹ 5,000 crore to transform India's Pharma MedTech sector from cost- to innovation-based growth by strengthening research and to promote industry-academia linkage for research and development in priority areas in drug discovery and development and medical devices. Under this, seven Centres of Excellence (CoEs) have been set up, one at each of the seven National Institutes of Pharmaceutical Education and Research (NIPERs), with total budgetary support to the tune of ₹ 700 crore, to create research infrastructure and promote R&D in identified areas. The CoEs are in the areas of anti-viral and anti-bacterial drug discovery and development, medical devices, bulk drugs, flow chemistry and continuous manufacturing, novel drug delivery system, phytopharmaceuticals and biological therapeutics, and have so far approved 104 research projects under the scheme and have filed two patents. The scheme also includes an outlay of ₹4,250 crore for support to industry and startups, including in collaboration with academia, for undertaking research and innovation projects in priority areas.

The PLI Scheme for Pharmaceuticals, which has a total budgetary outlay of ₹15,000 crore, aims to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector. It 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/KSMs/DIs other than those notified under the PLI Scheme for Bulk Drugs, thereby contributing to self-reliance. The scheme has enabled enhanced investment and production in eligible products. As of March 2025, the committed investment of ₹17,275 crore targeted over the six-year period of the scheme stands substantially exceeded with cumulative investment of ₹37,306 crore made by the scheme's third year, and cumulative sales of approved products of ₹2,66,528 crore have been made, including exports of ₹1,70,807 crore. The cumulative sales of ₹2,94,000 crore targeted over the six-year period of the scheme are expected to be exceeded in the scheme's fourth year.

The objective of the PLI Scheme for Bulk Drugs, which has a total budgetary outlay of ₹6,940 crore, is to improve self-reliance and reduce import dependence in critical KSMs, DIs and APIs. As of March 2025, the committed investment of ₹3,938.5 crore under projects approved under the scheme for investment over the six-year production period of the scheme stands substantially exceeded with cumulative investment of ₹4,570 crore made by the scheme's third year. Further, production capacity has been created for 25 APIs/KSMs/DIs.

Under the Bulk Drugs Park scheme, which has a total budgetary outlay of ₹3,000 crore, three 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 is over ₹ 6,300 crore, with Central assistance to the tune of ₹1,000 crore each for creation of common infrastructure facilities. These parks would offer land and utilities such as power, water, effluent treatment plant, steam, solid waste management, warehouse facilities at a subsidised rate. The State Implementing Agencies of the three States are also offering 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.

The Strengthening of Pharmaceutical Industry scheme supports realisation of the vision of Atmanirbhar Bharat through the following sub-schemes:

- (i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF): The scheme aims to strengthen the existing infrastructure facilities by providing financial assistance to pharmaceutical clusters for creation of common facilities. It helps create tangible assets as common facilities, such as testing labs, R&D labs, effluent treatment plants and training centres, thereby supporting the long-term viability and growth of the clusters by enabling them to develop and leverage shared resources. Under API-CF, projects with total grantin-aid to the tune of ₹ 139.33 crore to pharmaceutical clusters have been approved for creation of common facilities and are at various stages of execution. Once these common facilities are created, they are expected to provide access to common facilities to around 1,300 existing pharmaceutical units, besides catalysing the augmentation of capacities at these clusters through the setting up of new pharmaceutical units and expansion of existing units.
- (ii) Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS): The scheme aims to support upgrade of production facilities of small and medium pharmaceutical companies having average turnover of less than ₹ 500 crore, to attain the standards specified in the revised Schedule M to the Drugs Rules, 1945 and the World Health Organization − Good Manufacturing Practices (WHO-GMP), thereby improving their competitiveness, both domestically and globally. Under this, till 1.7.2025, support for upgrade to attain the said standards has been approved for 142 micro, small and medium pharmaceutical companies, with total sanctioned amount of ₹135.84 crore.

The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices has a total 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. So far, 21 greenfield projects have been commissioned, and production has started for 54 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 and ultrasound machines. Till March 2025, cumulative eligible sales ₹10,413.40 crore have been made under the scheme, including export sales worth ₹5,002 crore.

Under the Scheme for Promotion of Medical Devices 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 over ₹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.

The Scheme for Strengthening Medical Device Industry has been launched on 8.11.2024 with a financial outlay of ₹500 crore. It aims to strengthen the medical device industry by providing support in critical areas, including manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure, and industry promotion.

Enabled by these schemes, over the last six financial years, the export of drugs and pharmaceuticals has increased by 59% from US\$ 18,300 million in FY2018-19 to US\$ 29,046

million in FY2024-25, while that of medical devices has increased by 88%, from US\$ 2,138 million in FY2018-19 to US\$ 4,014 million in FY2024-25.

(d): Under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme, dedicated outlets known as Jan Aushadhi Kendras are opened across the country to provide medicines at prices that are about 50% to 80% lower than those of leading branded medicines in the market. Till 30.6.2025, a total of 16,912 Jan Aushadhi Kendras have been opened and on the average, about 10 to 12 lakh persons visit these Kendras daily and avail of quality medicines at affordable prices. 2,110 medicines and 315 surgicals, medical consumables and devices are under the scheme product basket, covering all major therapeutic groups, such as cardiovascular, anti-cancers, anti-diabetic, anti-infectives, anti-allergic and gastro-intestinal medicines and nutraceuticals. As a result of the scheme, in the last 11 years, estimated savings of about ₹38,000 crore have accrued to citizens in comparison to the prices of branded medicines. Further, the scheme has provided self-employment to over 16,000 persons, including over 6,800 women entrepreneurs.

(e): No such Mission is currently under consideration.
