GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO.1133
TO BE ANSWERED ON THE 25TH JULY 2025

Promotion of Pharmaceutical Research

1133. Shri P V Midhun Reddy:

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

(a) whether the Government has taken note of the lack of research in the pharmaceutical sector of the country, if so, the corrective measures taken in this regard;
(b) whether the Government is aware that, as per reports, new medicines, devices, diagnostics, patient aids, and monitoring tools continue to be imported due to lack of its development in the country and often reach the Indian patients several years after they are available to patients in the developed countries;
(c) if so, the steps taken/proposed to be taken by the Government to reduce import dependency and encourage local innovation; and
(d) whether the Government has provided an update regarding the proposed establishment of the campus of the National Institute of Pharmaceutical Education and Research (NIPER) in Visakhapatnam, Andhra Pradesh, which was sanctioned back in 2016, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (c): Taking note of the need to promote research in the pharmaceutical sector of the country and encourage local innovation, number of measures have been taken, including the following:

(i) 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;

(ii) The Department of Pharmaceuticals has set up seven NIPERs as institutes of national importance. These, besides imparting postgraduate and doctoral programmes, conduct high-end research in various pharmaceutical specialisations;
(iii) Support to research and innovation for development of innovative technologies and products for affordable healthcare by the Department of Biotechnology (DBT);
(iv) To encourage local innovations, the Drugs (Prices Control) Order, 2013 provides for exemption from price control to formulations developed through indigenous R&D for certain period, subject to fulfilment of certain conditions;
(v) Schemes and initiatives of the Biotechnology Industry Research Assistance Council (BIRAC), a public sector enterprise of the Department of Biotechnology, to support development of affordable products and technologies by startups, small and medium enterprises and large companies;
(vi) The constituent laboratories of the Council of Scientific and Industrial Research (CSIR) are engaged in development of new drugs, process technologies and diagnostics, necessary infrastructure and human resources;
(vii) The Department of Science and Technology is promoting R&D in the pharmaceutical sector through its Therapeutic Chemicals programme for the development key starting materials, intermediates and raw materials; and
(viii) The Indian Council of Medical Research provides financial assistance to different researchers and scientists working in its institutes under its intramural grants programme and to others through its extramural grants programme, for research in the fields of medicine, public health and allied disciplines.

To promote domestic manufacturing of new medicines, devices, diagnostics, patient aids, monitoring tools, etc. and reduce import dependency, number of measures have been taken through various schemes, including the following:

(i) 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);
(ii) PLI Scheme for Pharmaceuticals;
(iii) Scheme for Promotion of Bulk Drug Parks;
(iv) Strengthening of Pharmaceutical Industry scheme;
(v) PLI Scheme for Promoting Domestic Manufacturing of Medical Devices;
(vi) Scheme for Promotion of Medical Devices Parks; and
(vii) Scheme for Strengthening Medical Device Industry.

The PLI Scheme for Bulk Drugs, which has a total budgetary outlay of ₹6,940 crore, aims to avoid disruption in supply of critical active pharmaceutical ingredients (APIs) used to make critical drugs for which there are no alternatives by reducing supply disruption risk due to excessive dependence on single source. 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 scheme, cumulative sales of ₹1,817 crore have been reported over the period from FY2022-23 till FY2024-25, including exports of ₹455 crore, thereby avoiding imports worth ₹1,362 crore.

The PLI Scheme for Pharmaceuticals 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.

Under the Scheme for Promotion of Bulk Drug Parks, 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. Further, the scheme provides that applicants for allotment of land in the parks to set up units for manufacturing products prioritised in the PLI Scheme for Bulk Drugs will have priority in land allotment.
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 grant-in-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 ₹135.8 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): No NIPER has been sanctioned at Visakhapatnam.

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