GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA UNSTARRED QUESTION No. 988 # TO BE ANSWERED ON 29th JULY, 2025

National self-reliance in pharma industry

988 # Smt. Darshana Singh:

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

- (a) the number of units that have been approved so far under the Production Linked Incentive (PLI) scheme to encourage indigenous production of Active Pharmaceutical Ingredients and Bulk Drugs and the current stage of implementation;
- (b) the institutions, industrial units or Pharma Parks that have been planned to be established under the Pharma Innovation Policy with the purpose of promoting the drug research, innovation and production of high quality medicines; and
- (c) the new schemes, incentive packages and financial grants that have been launched for self-reliance in vaccine production and life saving medicines in the Country post COVID-19?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

- (a): The following PLI schemes are being implemented to promote indigenous production of Active Pharmaceutical Ingredients, which are referred to in common parlance as bulk drugs:
 - (i) Production Linked Incentive (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); and
 - (ii) PLI Scheme for Pharmaceuticals.

Under the PLI Scheme for Bulk Drugs, 48 projects for setting up greenfield manufacturing units for the production of 33 out of 41 APIs, KSMs and DIs covered by the scheme have been approved. 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.

Under the PLI Scheme for Pharmaceuticals, 38 applicants are approved for manufacturing APIs and DIs other than those notified under the PLI Scheme for Bulk Drugs.

Till March 2025, total domestic sales of API and DIs worth ₹22,658 crore have been made under the scheme at 132 manufacturing units, seven of which are greenfield units. This includes sales worth ₹1,582 crore of over 190 APIs and DIs that were manufactured domestically for the first time, thereby avoiding imports of the said value.

(b): To promote drug research and innovation and transform India's Pharma MedTech sector from cost- to innovation-based growth in priority areas, the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme has been launched with an outlay of ₹ 5,000 crore. 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.

With a view to promote production of high-quality medicines, under the PLI Scheme for Pharmaceuticals, PLI is available for the production of, among others, biopharmaceuticals, complex generic drugs, patented drugs or drugs nearing patent expiry, orphan drugs, autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, drugs not manufactured in India and other approved drugs. This has enabled enhanced investment and production in eligible products in both brownfield and greenfield industrial units. As of March 2025, cumulative sales of approved products of ₹2,04,451 crore have been made.

(c): With a view to promote production of high-quality medicines, under the PLI Scheme for Pharmaceuticals, PLI is available for the production of, among others, biopharmaceuticals, which include vaccines as well as other high-quality medicines as mentioned in the reply to part (b).
