

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

LOK SABHA
UNSTARRED QUESTION No. 313
TO BE ANSWERED ON THE 20th July, 2021

Operational Guidelines

**313. SHRI POCHA BRAHMANANDA REDDY:
SHRIMATI CHINTA ANURADHA:**

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

- (a) whether the Government had recently issued the Operational Guidelines for Production Linked Incentive Scheme of Pharmaceuticals;
- (b) if so, the details thereof;
- (c) the approved outlay of this scheme and the financial details thereof;
- (d) whether there are any sub-categories of products in the Pharma sector to avail the benefits under the scheme; and
- (e) if so, the details thereof?

ANSWER

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

(a) to (e): Yes, Sir. Operational Guidelines of Production Linked Incentive Scheme for Pharmaceuticals were issued on 1.6.2021. The objective of the scheme is 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. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The scheme covers pharmaceutical goods under following three categories-

Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates.

Category 3 (Drugs not covered under Category 1 and Category 2): Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

The total financial outlay of the scheme is Rs. 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales for 6 years. The tenure of the scheme is from FY 2020-2021 to 2028-29.

The Operational Guidelines of PLI Scheme for Pharmaceuticals are available on the website of the Department of Pharmaceuticals i.e. <http://pharmaceuticals.gov.in>.

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