

# Production Linked Incentive Scheme (PLI) for promotion of domestic manufacturing of APIs, KSMs and DIs

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## Background

- The Department of Pharmaceuticals earlier come out with the following two Production Linked Incentive schemes-
- Production Linked Incentive scheme for promotion of domestic manufacturing of critical Key Starting Materials, Drug Intermediates and Active Pharmaceutical Ingredients in India
- Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices
- Both the schemes were approved by the Cabinet on 20.03.2020 and the detailed guidelines for the implementation of the schemes were issued by the Department on 27.07.2020.
- These schemes have been constructed to incentivize large-scale manufacturing of critical bulk drugs and to build the required infrastructure for developing manufacturing clusters for across India. This aligns with the Government's mission for self-reliance (atmanirbharta).

## About Production Linked Incentive Scheme (PLI) for APIs, KSMs and DIs

- The 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. Production Linked Incentives of upto INR 6,940 crores

have been approved.

- A financial incentive will be given to eligible manufacturers of identified 41 eligible products which covers 53 APIs, for 6 years, committed investment and sales made by selected applicant for the eligible products.
- The rates will vary for Fermentation based products and Chemically Synthesized products.

### Objective:

The scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs

### Eligibility

Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India subject to committed investment and minimum annual production capacity.

### Tenure of the scheme

Tenure of the Production Linked Incentive Scheme is FY 2020-21 to FY 2029-30. Base year of the scheme is FY 2019-20.

### What is Key Starting Material (KSM)?

Key Starting Material is a raw material, intermediate or an API that is used in the production of an API & that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in house. KSMs are normally of defined chemical properties and structure

### What are Drug Intermediates (DIs)?

DIs are materials produced during intermediate steps in the synthesis of an Active Pharmaceutical Ingredient(API) that must undergo further molecular change or processing before it becomes an API

### What are Active Pharmaceutical Ingredients (APIs)

Active Pharmaceutical Ingredients (APIs) are any substance or combination of substances intended to be used in the manufacture of a drug(medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body.