



PRODUCT LINKED INCENTIVE

Pharmaceutical Industry

ABSTRACT

This report talks about the new PLI 2.0 and illustrates the key differences between PLI 1.0 and PLI 2.0 schemes initiated by the Government of India for Pharmaceutical Industry



CRETUM ADVISORY

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PLI 2.0 - The Second Phase

Background:

Production Linked Incentive (PLI) scheme in India is our Prime Minister Narendra Modi's government's subsidy plan to boost local manufacturing. It aims to give companies incentives on incremental sales from products manufactured in domestic units.

Drugs play a major role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country. Self-reliance in manufacturing of drugs is, therefore, highly desirable.

So 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.

Emergence of PLI 2.0:

The cabinet has now approved the Production Link Incentive (PLI) Scheme II to incentivise the Indian API industry to invest in the manufacture of APIs, KSMs, and DIs.

Unlike the earlier PLI scheme, which was aimed at boosting India's bulk drug security, the new scheme is aimed at encouraging the pharmaceutical industry to move up the value chain by investing in research and development (R&D) of complex generic medicines and novel therapeutics. This scheme has a wider range.

This is for enhancing manufacturing capabilities, diversifying the product mix to complex generics, patented drugs and going up the value chain, bringing some investment and eventually creating global champions. The new scheme is more extensive and could boost pharma production over a longer term.

It is a great intervention by the Government at the right time to encourage competition in the pharma sector by announcing PLI 2.0, which should bring down the prices and make healthcare more affordable and accessible under Ayushman Bharat and National Health Mission. The States will learn from the PLI 1.0 so that they can improve on the infrastructure like more Pharma and Medical Devices Parks to enable existing units to expand, Startups and Entrepreneurs to enter the business and go global in the interest of consumers.

Expectations:

The scheme is expected to generate 20,000 direct jobs and 80,000 indirect employment for both skilled and unskilled personnel, as a result of growth in the sector, the release said.

The scheme is also expected to bring in investment of Rs 15,000 crore in the pharmaceutical sector.

The scheme is expected to promote the production of high value products in the country and increase the value addition in exports. Total incremental sales of Rs.2,94,000 crore and total incremental exports of Rs.1,96,000 crore are estimated during six years from 2022-23 to 2027-28.

The PLI scheme is further expected to promote innovation for development of complex and high-tech products including products of emerging therapies and in-vitro diagnostic services as also self-reliance in important drugs.

Objective:

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.

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PLI 1.0 & PLI 2.0 Comparison

SN	Parameters	PLI 1.0	PLI 2.0																						
1	Scheme Tenure	The tenure of the scheme is from FY 2020-21 to FY 2029-30	FY 2020-21 to FY 2028-29																						
2	Gross Incentives outlay	Rs. 6,940 crore	Rs. 15,000 crore																						
4	Base Year	FY 2019-20	FY 2019-20																						
5	Category of Goods	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Target Segments</th> <th style="width: 70%;">Products Covered</th> </tr> </thead> <tbody> <tr> <td>Fermentation based KSMs/Drug Intermediates</td> <td> <ul style="list-style-type: none"> Penicillin G 7-ACA Erythromycin Thiocynate (TIOC) Clavulanic Acid </td> </tr> <tr> <td>Fermentation based niche KSMs/Drug Intermediates/APIs</td> <td> <ul style="list-style-type: none"> Neomycin Gentamycin Betamethasone Dexamethasone Prednisolone Rifampicin Vitamin B1 Clindamycin Base Streptomycin Tetracycline </td> </tr> <tr> <td>Key Chemical Synthesis based KSMs/Drug Intermediates</td> <td> <ul style="list-style-type: none"> 1,1 Cyclohexane Diacetic Acid (CDA) 2-Methyl-5Nitro-Imidazole (2-MNI) Dicyandiamide (DCDA) Para amino phenol </td> </tr> <tr> <td>Other Chemical Synthesis based KSMs/Drug Intermediates/APIs</td> <td> <ul style="list-style-type: none"> Meropenem Atorvastatin Olmesartan Valsartan Losartan Levofloxacin Sulfadiazine Ciprofloxacin Ofloxacin Norfloxacin Artesunate Telmisartan Aspirin Diclofenac Sodium Levetiracetam Carbidopa Ritonavir Lopinavir Acyclovir Carbamazepine Oxcarbazepine Vitamin B6 Levodopa </td> </tr> </tbody> </table>	Target Segments	Products Covered	Fermentation based KSMs/Drug Intermediates	<ul style="list-style-type: none"> Penicillin G 7-ACA Erythromycin Thiocynate (TIOC) Clavulanic Acid 	Fermentation based niche KSMs/Drug Intermediates/APIs	<ul style="list-style-type: none"> Neomycin Gentamycin Betamethasone Dexamethasone Prednisolone Rifampicin Vitamin B1 Clindamycin Base Streptomycin Tetracycline 	Key Chemical Synthesis based KSMs/Drug Intermediates	<ul style="list-style-type: none"> 1,1 Cyclohexane Diacetic Acid (CDA) 2-Methyl-5Nitro-Imidazole (2-MNI) Dicyandiamide (DCDA) Para amino phenol 	Other Chemical Synthesis based KSMs/Drug Intermediates/APIs	<ul style="list-style-type: none"> Meropenem Atorvastatin Olmesartan Valsartan Losartan Levofloxacin Sulfadiazine Ciprofloxacin Ofloxacin Norfloxacin Artesunate Telmisartan Aspirin Diclofenac Sodium Levetiracetam Carbidopa Ritonavir Lopinavir Acyclovir Carbamazepine Oxcarbazepine Vitamin B6 Levodopa 	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Category</th> <th style="width: 60%;">Products Covered*</th> <th style="width: 25%;">Rate of Incentives (As a percentage of incremental sales over base year)</th> </tr> </thead> <tbody> <tr> <td>I.</td> <td> <ul style="list-style-type: none"> 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 </td> <td> <ul style="list-style-type: none"> Year 1 - Year 4: 10% Year 5: 8% Year 6 : 6% </td> </tr> <tr> <td>II.</td> <td> <ul style="list-style-type: none"> Active Pharmaceuticals Ingredients / Key Starting Materials / Drug Intermediates </td> <td> <ul style="list-style-type: none"> Year 1 to Year 4: 10% Year 5: 8% Year 6 : 6% </td> </tr> <tr> <td>III.</td> <td> <ul style="list-style-type: none"> 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 </td> <td> <ul style="list-style-type: none"> Year 1 to Year 4: 5% Year 5: 4% Year 6 : 3% </td> </tr> </tbody> </table>	Category	Products Covered*	Rate of Incentives (As a percentage of incremental sales over base year)	I.	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Year 1 - Year 4: 10% Year 5: 8% Year 6 : 6% 	II.	<ul style="list-style-type: none"> Active Pharmaceuticals Ingredients / Key Starting Materials / Drug Intermediates 	<ul style="list-style-type: none"> Year 1 to Year 4: 10% Year 5: 8% Year 6 : 6% 	III.	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Year 1 to Year 4: 5% Year 5: 4% Year 6 : 3%
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<p><i>*Sub-products (Names of the Drugs) under the products mentioned above are yet to be released by the Government.</i></p>																									

6	Eligibility	<ul style="list-style-type: none"> Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India. Eligibility shall be subject to threshold investment in green field projects Eligibility under the scheme shall not affect eligibility under any other scheme and vice versa. <table border="1" data-bbox="292 613 1093 1489"> <thead> <tr> <th colspan="3">Eligibility Threshold Criteria</th> </tr> <tr> <th>S. No.</th> <th>Segment</th> <th>Threshold Investment</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Fermentation based 04 KSMs /Drug Intermediates</td> <td>Rs. 400 crore</td> </tr> <tr> <td>2</td> <td>Fermentation based 10 niche KSMs / Drug Intermediates / APIs</td> <td>Rs. 50 crore</td> </tr> <tr> <td>3</td> <td>Key Chemical Synthesis based 04 KSMs /Drug Intermediates</td> <td>Rs. 50 crore</td> </tr> <tr> <td>4</td> <td>Other 23 Chemical Synthesis based KSMs / Drug Intermediates / APIs</td> <td>Rs. 20 crore</td> </tr> </tbody> </table> <p>Comprehensive list of eligibility criteria, please click here</p>	Eligibility Threshold Criteria			S. No.	Segment	Threshold Investment	1	Fermentation based 04 KSMs /Drug Intermediates	Rs. 400 crore	2	Fermentation based 10 niche KSMs / Drug Intermediates / APIs	Rs. 50 crore	3	Key Chemical Synthesis based 04 KSMs /Drug Intermediates	Rs. 50 crore	4	Other 23 Chemical Synthesis based KSMs / Drug Intermediates / APIs	Rs. 20 crore	<ul style="list-style-type: none"> Based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales as mentioned below <table border="1" data-bbox="1130 399 1999 1507"> <thead> <tr> <th>Group of Participants</th> <th>Minimum Cumulative Investment per participant (Rs. Crore)</th> <th>Minimum Percentage Growth in Sales (Year on Year)</th> </tr> </thead> <tbody> <tr> <td>Group A (GMR ≥ Rs. 5,000 Cr.)</td> <td>Rs. 1,000 crore over 5 years. FY 2021-22: 200 FY 2022-23: 400 FY 2023-24: 600 FY 2024-25: 800 FY 2025-26: 1000</td> <td rowspan="2">For the first year of production, participants shall have to achieve Minimum threshold sales which will be specified by value for each Group in the scheme guidelines.</td> </tr> <tr> <td>Group B (GMR between 500 Cr. and 5000 Cr.)</td> <td>Rs. 250 crore over 5 years. FY 2021-22: 50 FY 2022-23: 100 FY 2023-24: 150 FY 2024-25: 200 FY 2025-26: 250</td> </tr> <tr> <td>Group C (GMR ≤ 500 Cr.)</td> <td>Rs. 50 crore over 5 years. FY 2021-22: 10 FY 2022-23: 20 FY 2023-24: 30 FY 2024-25: 40 FY 2025-26: 50</td> <td>For subsequent years, the participants have to achieve a minimum percentage growth of 7% Year on Year.</td> </tr> </tbody> </table> <p><i>GMR – Global Manufacturing Revenue</i></p> <ul style="list-style-type: none"> The selected participants in the scheme will be eligible for incentives on incremental sales of pharmaceutical goods based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales. 	Group of Participants	Minimum Cumulative Investment per participant (Rs. Crore)	Minimum Percentage Growth in Sales (Year on Year)	Group A (GMR ≥ Rs. 5,000 Cr.)	Rs. 1,000 crore over 5 years. FY 2021-22: 200 FY 2022-23: 400 FY 2023-24: 600 FY 2024-25: 800 FY 2025-26: 1000	For the first year of production, participants shall have to achieve Minimum threshold sales which will be specified by value for each Group in the scheme guidelines.	Group B (GMR between 500 Cr. and 5000 Cr.)	Rs. 250 crore over 5 years. FY 2021-22: 50 FY 2022-23: 100 FY 2023-24: 150 FY 2024-25: 200 FY 2025-26: 250	Group C (GMR ≤ 500 Cr.)	Rs. 50 crore over 5 years. FY 2021-22: 10 FY 2022-23: 20 FY 2023-24: 30 FY 2024-25: 40 FY 2025-26: 50	For subsequent years, the participants have to achieve a minimum percentage growth of 7% Year on Year.
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7	Quantum of Incentive	<p>Financial incentive under the scheme shall be provided on sales of 41 products mentioned above at the rates given below:</p> <ul style="list-style-type: none"> For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%. For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%. 	<p>The incentive allocation among the Target Groups is as follows-</p> <ul style="list-style-type: none"> Group A: Rs 11,000 crore Group B: Rs 2,250 crore Group C: Rs 1,750 crore 																													

Open Points still to be Answered

- What are the sub-products (Names of the Drugs) under the products mentioned in PLI 2.0 ?
- IFCI was the Product Management Agency (PMA) for PLI 1.0. Who will be appointed as PMA for PLI 2.0 ?
- When will the application window open and for how many days ?
- What will be the guidelines regarding procedures to be followed to avail the scheme ?

Need for Cretum Advisory in the PLI 2.0

Cretum Advisory is assisting the companies in identifying the product with due discussion with the PMA

Preparation of representation to include the products and projects under the PLI 2.0

Assistance in decoding the scheme

Assistance in preparation of the application and filing of the same

Indian Entity Incorporation and Regulatory Compliance

Post the filing, due discussion with the PMA to get the same approved

Services of Cretum Advisory in Invest India projects

Opportunity Study

Partner Search

Location Analysis

Greenfield Set-up

Indian Entity Incorporation and Regulatory Compliance

Market Intelligence & Industry Analysis

Array of Services Offered to Corporates by Cretum Advisory

Cross Border Investment

Strategy Advisory

Mergers and Acquisitions & Fund Raising

Accounting and Assurance

Legal Services

Tax Advisory

- In light of radically shifting customer and market dynamics, leading disruptive innovation in their sector, embarking on end-to-end digital transformations, pursuing and optimizing inorganic growth strategies, defining and implementing organic growth strategies, optimizing their supply chain and setting their global tax agenda. **Cretum helps answering the “What?” and the “How?” questions on the agenda to help deliver long-term value across our clients.**
- Through our service lines — Assurance, Consulting, fund raising, Mergers and acquisitions, Cross Border Investment policy, Transactions, Tax and Strategic advisory — we help our clients capitalize on transformative opportunities. We also help them fulfil regulatory requirements, keep investors informed and meet the needs of all of their stakeholders. And in a fast-changing world, we give them the support they need to be effective today and create long-term value for tomorrow.
- Our expert team provide intelligence only available through our network, and facilitate the right interactions for you, allowing you to influence your business strategically and operationally and will help you connect with live business opportunities in the Uttar Pradesh market.
- 7 Managing Partners with cumulative 100 years+ of experience majorly in big 4 consulting companies

Firm Leaders



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Devan Gupta is the co-founder of Cretum Advisory and has over 13 years of experience in the field of audit, assurance and business advisory, served both Public and Private Limited Companies



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