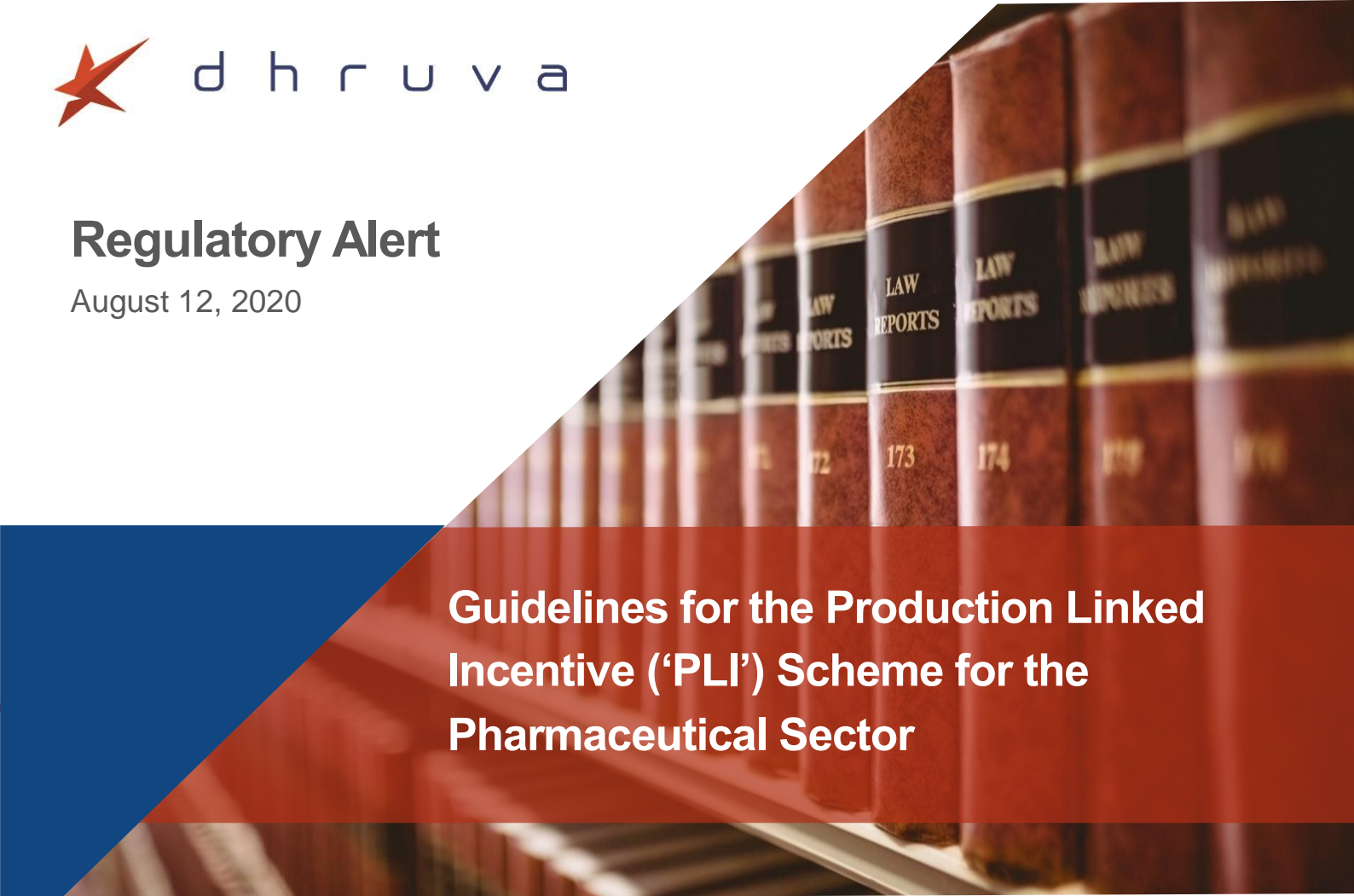


# Regulatory Alert

August 12, 2020



## Guidelines for the Production Linked Incentive ('PLI') Scheme for the Pharmaceutical Sector

With the objective of promoting the domestic manufacturing of critical Key Starting Materials ('KSMs'), Drug Intermediaries ('DIs') and Active Pharmaceutical Ingredients ('APIs') in India, the Government has notified<sup>1</sup> the Production Linked Incentive Scheme ('Scheme') for Pharmaceutical Sector. In furtherance of the said Notification, on July 27, 2020, the Government issued Guidelines for the Scheme for the pharmaceutical sector, providing a detailed framework to avail the incentive.

### Background

- The Indian pharmaceutical industry is the 3<sup>rd</sup> largest in the world by volume and the 14<sup>th</sup> largest in terms of value. However, India is significantly dependent on imports of certain basic raw materials used in manufacturing finished dosage formulations.
- The Covid-19 pandemic has posed unprecedented challenges, disrupting supply chains globally. The need to reduce dependence on imports and to ensure the uninterrupted supply of drugs has promoted the need to be self-reliant or '*aatmanirbhar*'.
- Hence, in consonance with the 'Aatmanirbhar Bharat' vision of Prime Minister Narendra Modi, the Scheme has been introduced by the Department of Pharmaceuticals ('DoP') and the Ministry of Chemicals and Fertilizers to promote the domestic manufacturing of KSMs/ DIs/ APIs.
- This alert provides an overview of certain critical provisions of the Scheme and Guidelines.

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<sup>1</sup> Notification No. 31026/16/2020 dated July 21, 2020



## Key Features of the Scheme

- The Government seeks to provide aggregate financial incentive amounting to INR 6,940 crores under this Scheme.
- The Scheme provides incentives for 41 specified products comprising of 14 fermentation and 27 chemical synthesis based KSMS/ DIs/ APIs. The eligible products description with corresponding production capacity, investment threshold and incentive amount is provided in the Annexure A.
- The applications to register under this Scheme shall be filed within 120 days from the date of issuance of these Guidelines.
- The maximum number of selected applicants for each eligible product will be between two and four depending on the nature of the product.
- Incentives shall be computed as a percentage of domestic net sales. The incentive rates are as under:

Fermentation based products	
Financial Year	Rate of Incentive
FY 2023-24 to 2026-27	20%
FY 2027-28	15%
FY 2028-29	5%

Chemical synthesis-based products	
Financial Year	Rate of Incentive
FY 2022-23 to 2027-28	10%

- Net sales shall be computed either as per the sale price quoted in the application, or the actual sale price, whichever is lower.
- In case of in-house consumption, net sales shall be computed either as per the sale price quoted in the application, or the actual cost of production, whichever is lower.
- The Scheme provides for a maximum incentive amount which shall be payable annually to each selected applicant for each eligible product.
- Incentives shall only be given only for eligible products manufactured in the greenfield project for which the investment was undertaken on or after April 01, 2020.
- Applicants could be companies registered in India, limited liability partnerships, partnership firms or sole-proprietorship concerns, proposing to manufacture eligible products.
- Eligibility under the Scheme shall not affect eligibility under any other scheme and vice-a-versa.

## Eligibility Conditions

Applicants must fulfil the following two-fold criteria to be eligible under the Scheme and to avail the incentive: (1) Eligibility criteria for selection of an applicant, and (2) Eligibility criteria for availing incentive.

Eligibility criteria for selection of an Applicant	
Criteria	Particulars
Investment criteria to qualify as a greenfield project	<ul style="list-style-type: none"> <li>• Investment shall either be in a new production facility or a new plant on the premises of an existing production facility</li> <li>• Investment shall be made on or after April 1, 2020</li> </ul>



### Eligibility criteria for selection of an Applicant

<b>Net Worth</b>	<ul style="list-style-type: none"> <li>As on the application date, net worth of the Applicant (including the Group Companies) shall be atleast 30% of proposed investment</li> <li>Net worth includes the net worth of group companies</li> </ul>
<b>Domestic Value Addition ('DVA')</b>	<p>DVA is the proportion of the 'net sales turnover less the value of imported materials and services' over 'net sales turnover'.</p> <p>Minimum DVA proportion shall be:</p> <ul style="list-style-type: none"> <li>Fermentation based product – at least 90%</li> <li>Chemical synthesis based product – at least 70%</li> </ul>
<b>Financial standing</b>	Has not been declared bankrupt, wilful defaulter, defaulter or fraudster

### Eligibility criteria for availing incentive

Criteria	Particulars
<b>Basic threshold</b>	<ul style="list-style-type: none"> <li>Minimum investment<sup>#</sup> threshold - INR 20 to 400 crores*</li> <li>Minimum annual production capacity – 10 to 8000 MT*</li> </ul>
<b>Additional threshold criteria</b>	<ul style="list-style-type: none"> <li>In the case of multiple products, both of the above thresholds must be satisfied for each product individually</li> <li>Commitments made in excess of the minimum threshold should also be met in order to avail benefits</li> </ul>
<b>DVA</b>	<ul style="list-style-type: none"> <li>DVA threshold discussed above is to be maintained throughout the claim period, subject to permitted relaxation</li> <li>Relaxed thresholds: <ul style="list-style-type: none"> <li>Fermentation-based product – DVA between 80 to 90%</li> <li>Chemical synthesis-based product – DVA between 60 to 70%</li> <li>Relaxation allowed for an aggregate period of 12 months across the claim period</li> <li>Applicants will be entitled to 50% of the eligible incentive where relaxed DVA has been achieved</li> </ul> </li> </ul>
<b>Financial standing</b>	Has not been declared bankrupt, wilful defaulter, defaulter or fraudster
<b>Carry forward</b>	If the selected Applicant is not able to claim the incentive, then such incentive as is not claimed shall lapse and need not be carried forward to subsequent year/s.

\* Minimum eligible investment and production capacity for all 41 products has been enlisted in Annexure-A

#### # Investment Criteria:

- Investment to include expenditure incurred on acquiring new plant, machinery, equipment, associated operational utilities, research and development facility related to the eligible product/s and the costs incurred on the construction of building where new plants have been installed.



However, expenditure incurred on the land as well as on used assets shall not qualify for computing the investment threshold.

- Expenditure on compound walls, internal roads and other associated infrastructure of the building shall be restricted to 20% of the investment in plant and machinery. Further, expenditure on guest house, office building, residential colonies, etc shall not be eligible.

### Key mechanisms for filing the Application

- Applications under this Scheme shall be made to the Project Management Agency ('PMA') through an online portal (yet to be made available) or in physical form (when portal not available).
- An applicant is eligible to file applications for more than one eligible product. In respect of each product, separate application form needs to be submitted along with a separate fee<sup>2</sup>.
- All of the applications will be finalised within 90 days after the closure of the application window and the selected Applicants will be issued an approval letter by the PMA.
- On issuance of the approval letter, the selected Applicant shall submit a bank guarantee of a sum amounting to 1% of the committed investment in favour of the DoP. The bank guarantee shall be released once 90% of the committed investment has been made in the project.

### Criteria for selection and approval

- All eligible applicants shall be ranked based on marks granted as per the following criteria:

Criteria	Weightage
Annual production capacity	35
Quoted sale price	65

- The Applicant with the highest committed annual capacity will be awarded 35 marks and the other Applicants shall be awarded proportionately.
- Similarly, the Applicant quoting lowest sale price will obtain 65 marks and the other Applicants will be awarded proportionately.
- The Applicant with the highest score (aggregate of the scores derived for production capacity and sales price) shall be ranked 1<sup>st</sup> and so on.
- Also, the maximum number of Applicants to be selected shall be subject to committed annual production capacity as well as the maximum amount of incentive available for each eligible product.

### Disbursement of Incentives

- Applicants shall be eligible to claim the incentive only after investing the committed investment amount and after setting up a plant for committed annual production capacity, as per the approval granted.
- Applicants shall complete the investment prior to commercial production.
- Applicants may submit claims for disbursement to the PMA either on a half yearly basis or on an annual basis, along with a calculation of DVA and a certificate from a statutory auditor or an independent Chartered Accountant, as applicable.

<sup>2</sup> Application fee is in the range of INR 50,000 to INR 1,00,000 based on the nature of the product.



- The claims for disbursement shall be filed within 9 months from the end of the relevant financial year.
- PMA shall process claim within 60 days and shall disburse funds after receiving approval from the Empowered Committee ('EC').

### Dhruva Comments

- The Government is taking various steps to fulfil its dream of making India Aatma-Nirbhar as well as to promote its Make-in-India policy. This Scheme is a step in that direction.
- This Scheme, along with various other incentives provided under various laws including the concessional tax regime framework of 15% laid down under section 115BAB of the Income-tax Act, 1961, could be a game changer for pharmaceutical industry planning to undertake capital expenditure and to expand themselves.
- It must be noted that the Scheme provides for a tight schedule, therefore interested organisations must commence strategising on proposed business plans on a priority basis. The Applicants will also have to undertake detailed cost-benefit analysis, factoring the financial incentive before arriving at any conclusion.

### How can Dhruva assist?

Here at Dhruva, we have significant expertise in the tax and regulatory aspects of the pharmaceutical sector and will be happy to provide assistance in understanding the various nuances of the Scheme, helping you to plan and strategise your operations in an effective manner. An illustrative list of how we can assist is depicted below:





## Annexure A: List of eligible products

### I. Chemical synthesis-based products

Sr No.	Name of product	Minimum annual production capacity (in MT)	Threshold investment (in crores)	Maximum selected applicants	Maximum incentive for each selected applicant (in crores) <sup>3</sup>
<b>Key chemical synthesis-based products</b>					
1	1,1 Cyclohexane Diacetic Acid	1500	50	4	10
2	2-Methyl-5 Nitro Imidazole	800	50	4	10
3	Dicyandiamide	8000	50	4	10
4	Para amino phenol	8000	50	4	10
<b>Chemical synthesis-based niche products</b>					
5	Meropenem	10	20	4	2.5
6	Atorvastatin	30	20	4	2.5
7	Olmesartan	25	20	4	2.5
8	Valsartan	25	20	4	2.5
9	Losartan	80	20	4	2.5
10	Levofloxacin	115	20	4	2.5
11	Sulfadiazine	20	20	4	2.5
12	Ciprofloxacin	300	20	4	2.5
13	Ofloxacin	100	20	4	2.5
14	Norfloxacin	15	20	4	2.5
15	Artesunate	35	20	4	2.5
16	Telmisartan	80	20	4	2.5
17	Aspirin	2800	20	4	2.5
18	Diclofenac Sodium	175	20	4	2.5
19	Levetiracetam	140	20	4	2.5
20	Carbidopa	2	20	4	2.5
21	Ritonavir	5	20	4	2.5
22	Lopinavir	7	20	4	2.5
23	Acyclovir	175	20	4	2.5
24	Carbamazepine	65	20	4	2.5
25	Oxcarbazepine	65	20	4	2.5
26	Vitamin B6	35	20	4	2.5
27	Levodopa	10	20	4	2.5

<sup>3</sup> Subject to certain conditions, the incentive granted to an applicant can exceed the maximum amount as provided in the Annexure



## II. Fermentation based products

Sr No.	Name of product	Minimum annual production capacity (in MT)	Threshold investment (in crores)	Maximum selected applicants	Maximum incentive for each selected applicant (in crores) <sup>4</sup>		
					Year 1-4	Year 5	Year 6
<b>Key fermentation-based products</b>							
1	Penicillin G	5000	400	2	120	90	30
2	7-ACA	1000	400	2	120	90	30
3	Erythromycin Thiocynate	800	400	2	60	45	15
4	Clavulanic Acid	1.5 Lakh kilogram	400	2	60	45	15
<b>Fermentation-based niche products</b>							
5	Neomycin	175	50	2	10	7.5	2.5
6	Gentamycin	40	50	2	10	7.5	2.5
7	Betamethasone	2	50	2	10	7.5	2.5
8	Dexamethasone	2	50	2	10	7.5	2.5
9	Prednisolone	15	50	2	10	7.5	2.5
10	Rifampicin	100	50	2	10	7.5	2.5
11	Vitamin B1	200	50	2	10	7.5	2.5
12	Clindamycin Base	60	50	2	10	7.5	2.5
13	Streptomycin	50	50	2	10	7.5	2.5
14	Tetracycline	450	50	2	10	7.5	2.5

<sup>4</sup> Subject to certain conditions, the incentive granted to an applicant can exceed the maximum amount as provided in the Annexure



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