

TAX FLASH NEWS

2 June 2021

Operational guidelines for Production Linked Incentive scheme (PLI scheme) for Pharmaceuticals

With an aim to enhance India’s manufacturing capabilities in pharmaceutical sector and create global champions from India who have the potential to grow in size and scale using cutting edge technology, the Government of India had approved PLI scheme for pharmaceutical sector. Notification in this regard was thereafter issued by Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) on 3 March 2021. The operational guidelines detailing therein the process, requirements, etc. to be followed by businesses while making an application has been released. The application window for the scheme is open for a period of 60 days i.e. from **2 June 2021 to 31 July 2021**.

Key highlights of the guidelines are as under –

1. **Applicant** – Company registered in India, Limited Liability Company (‘LLP’), Partnership firm, Proprietary firm.
2. **Base year** – FY 2019-20
3. **Application window** – 2 June 2021 to 31 July 2021
4. **Target segment** –

Product category

Category 1	Category 2	Category 3
Bio pharmaceuticals	Active Pharma Ingredients (APIs) / Key Starting Materials (KSMs) and / Drug Intermediaries (DIs)	Repurposed Drugs
Complex Generic Drugs		Auto-immune drugs, anti-cancer drugs, anti diabetic drugs, anti infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs
Patented drugs or drugs nearing patent expiry		In-vitro diagnostic devices (IVDs)
Cell based or Gene therapy products		Other drugs not manufactured in India
Orphan drugs		Other drugs as approved*
Special Empty Capsules like HPMC, Pullulan, enteric etc.		
Complex excipients		
Phyto-pharmaceuticals		
Other drugs as approved*		
<p><i>Decision will be taken by DoP to include any drug based on requirement, Central Drugs Standard Control Organisation (‘CDSCO’) approvals, Technical Committee (‘TC’) opinion which shall take into account the current levels of production, availability, etc. The decision of DoP shall be aligned with the objectives of the scheme.</i></p>		

5. Application, evaluation, and selection criteria

a) Application –

- Application shall be filed within three groups
- The groups are classified based on Global Manufacturing Revenue ('GMR') for FY 2019-20 of pharmaceutical goods and/or in-vitro Diagnostic medical devices

Group	GMR
A	More than or equal to INR 5000 crore
B	Between INR 500 crore (inclusive) to INR 5000 crore
C	Less than INR 500 crore (sub-group of MSME in this group)

b) Evaluation criteria –

Selection of the applicants under each group shall be determined basis defined weightage allocated against each identified parameter for pharmaceutical goods and In-Vitro Diagnostic Medical Devices respectively

i. Criteria for Pharmaceutical goods

Group	Selection parameters	Weightage
A & B	Gross manufacturing investment ('GMI') of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
	R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020.	40%
C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021	30%
	GMR from pharmaceutical goods in FY 2019-2020	40%
C (MSME)	Number of manufacturing plants in India owned by applicant/group company and approved by USFDA / EDQM / UK MHRA / PMDA / Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021	50%
	Total Investment Committed by the applicant under the scheme	50%

ii. Criteria for In-Vitro Diagnostic Medical Devices

Group	Selection parameters	Weightage
A, B & C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved by USFDA / EU (CE) / UK MHRA / PMDA / Health Canada / TGA / CDSCO as on 01.04.2021	30%
	GMR from in vitro diagnostic medical devices in FY 2019-2020	40%

c) Selection criteria –

- i. Eligible applicants shall be ranked basis the evaluation criteria. Selection shall be in order of ranking**
- ii. Ranking shall be given as under –**
 - Applicant having highest gross manufacturing investment shall be awarded 30 marks, and proportionate marks other shall be awarded to other participants
 - Applicant having highest ANDA/NDA shall be awarded 30 marks and others shall be proportionately awarded marks
 - Applicant with highest percentage of total R&D expenditure vis-à-vis GMR shall be awarded 40 marks and other to be awarded proportionately
 - Similar procedure [i.e. procedure described in (1), (2) and (3) above] for ranking shall be followed for other groups i.e. B, C and C (MSME) and for parameters prescribed for In-vitro diagnostic medical devices
- iii. Number of applicants to be selected**

Group	No. of applicant to be selection	Condition
A	11 participants	Maximum 4 MNCs
B	9 participants	Maximum 3 MNCs
C	35 participants	<ul style="list-style-type: none"> • Minimum 20 MSMEs • Minimum of 5 in-vitro diagnostic medical device manufacturer

6. Incentive

a) Eligibility –

- Eligibility for incentive shall be based on incremental sales of eligible products based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales

Break-up of minimum cumulative investment criteria

Year	Minimum cumulative investment per participants			
	Group A	Group B	Group C	Group C (MSME)
Investment over 5 year period	INR 1000 crore over 5 years	Rs. 250 crore over 5 years	Rs. 50 crore over 5 years	Committed Investment (CI) over 5 years

Eligible investment – expenses incurred in relation to eligible products on

- New plant, machinery, equipment and associated utilities
- *Research and Development (R&D)*
- *Transfer of Technology (ToT) agreements*
- *Product registration*
- *Building (Associated Infrastructure – upto 20%,*

Excludes *guest house building, recreational facilities, office building, residential colonies etc. and land; second hand/ used/ refurbished plant, machinery, equipment, utilities or research and development equipment*

Includes - *All non-creditable taxes and duties would be included in such expenditure.*

Percentage growth in sales criteria

Incentive Year	Threshold sales criteria			
	Group A	Group B	Group C	Group C (MSME)
FY 2022-23	Greater than INR 50 crore	Greater than INR 10 crore	Greater than INR 1 crore	Greater than INR 50 lakhs
FY 2023-24 onwards	7 per cent growth over actual sales of eligible product in previous financial year			

b) Quantum and rate of incentive

- Incentive under the scheme shall be calculated on the incremental sales of the eligible products i.e. Incentive = Net incremental sales x Rate of incentive
- Annual incentive allocation shall be made for each participant within the total incentive allocation per participant fixed for the entire tenure of the scheme

Ceiling for incentive

Group	Incentive ceiling	Additional incentive ceiling	Total incentive	Maximum allocated Incentive
A	INR 1000 crore	INR 200 crore	INR 1200 crore	INR 11000 crore
B	INR 250 crore	INR 50 crore	INR 300 crore	INR 2250 crore
C	INR 50 crore	INR 10 crore	INR 60 crore	INR 1750 crore

Rate of incentive – calculated on incremental sales over base year of eligible product category

Financial year	Incentive rate	
	Product category 1 and 2	Product category 3
2022-23 to 2025-26	10%	5%
2026-27	8%	4%
2027-28	6%	3%

Our comments

Pharma sector has been identified as one of the key sector to accomplish the Government's vision of making India self-reliant and also make Indian manufacturer penetrate the global value chain. With the total financial outlay of INR 15000 crore, the PLI scheme for pharma provides a much-needed impetus to the sector's growth in India.

The operational guidelines have laid down a detailed procedure for making the application. It is important to note that, the window for filing the application is open and industry needs to quickly review its investment strategy as the window is expected to close within 60 days i.e. by 31 July 2021.

KPMG in India addresses:

Ahmedabad

Commerce House V, 9th Floor,
902, Near Vodafone House, Corporate
Road,
Prahlad Nagar,
Ahmedabad – 380 051.
Tel: +91 79 4040 2200

Bengaluru

Embassy Golf Links Business Park,
Pebble Beach, 'B' Block,
1st & 2nd Floor,
Off Intermediate Ring Road, Bengaluru –
560071
Tel: +91 80 6833 5000

Chandigarh

SCO 22-23 (1st Floor),
Sector 8C, Madhya Marg,
Chandigarh – 160 009.
Tel: +91 172 664 4000

Chennai

KRM Towers, Ground Floor,
1, 2 & 3 Floor, Harrington Road,
Chetpet, Chennai – 600 031.
Tel: +91 44 3914 5000

Gurugram

Building No.10, 8th Floor,
DLF Cyber City, Phase II,
Gurugram, Haryana – 122 002.
Tel: +91 124 307 4000

Hyderabad

Salarpuria Knowledge City,
6th Floor, Unit 3, Phase III,
Sy No. 83/1, Plot No 2, Serilingampally
Mandal,
Ranga Reddy District,
Hyderabad – 500 081.
Tel: +91 40 6111 6000

Jaipur

Regus Radiant Centre Pvt Ltd.,
Level 6, Jaipur Centre Mall,
B2 By pass Tonk Road,
Jaipur – 302 018.
Tel: +91 141 - 7103224

Kochi

Syama Business Centre,
3rd Floor, NH By Pass Road,
Vytilla, Kochi – 682 019.
Tel: +91 484 302 5600

Kolkata

Unit No. 604,
6th Floor, Tower – 1,
Godrej Waterside,
Sector – V, Salt Lake,
Kolkata – 700 091.
Tel: +91 33 4403 4000

Mumbai

1st Floor, Lodha Excelus,
Apollo Mills,
N. M. Joshi Marg,
Mahalaxmi,
Mumbai – 400 011.
Tel: +91 22 3989 6000

Noida

Unit No. 501, 5th Floor,
Advant Navis Business Park,
Tower-A, Plot# 7, Sector 142,
Expressway Noida,
Gautam Budh Nagar,
Noida – 201 305.
Tel: +91 0120 386 8000

Pune

9th floor, Business Plaza,
Westin Hotel Campus, 36/3-B,
Koregaon Park Annex,
Mundhwa Road, Ghorpadi,
Pune – 411 001.
Tel: +91 20 6747 7000

Vadodara

Ocean Building, 303, 3rd Floor,
Beside Center Square Mall,
Opp. Vadodara Central Mall,
Dr. Vikram Sarabhai Marg,
Vadodara – 390 023.
Tel: +91 265 619 4200

Vijayawada

Door No. 54-15-18E,
Sai Odyssey,
Gurunanak Nagar Road, NH 5,
Opp. Executive Club, Vijayawada,
Krishna District,
Andhra Pradesh – 520 008.
Tel: +91 0866 669 1000

home.kpmg/in



home.kpmg/in/socialmedia



The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

KPMG Assurance and Consulting Services LLP, Lodha Excelus, Apollo Mills Compound, NM Joshi Marg, Mahalaxmi, Mumbai - 400 011
Phone: +91 22 3989 6000, Fax: +91 22 3983 6000

© 2021 KPMG Assurance and Consulting Services LLP, an Indian Limited Liability Partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved.

KPMG (Registered) (a partnership firm with Registration No. BA- 62445) converted into KPMG Assurance and Consulting Services LLP (a Limited Liability partnership firm) with LLP Registration No. AAT-0367 with effect from July 23, 2020.

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.

This document is meant for e-communication only.