

सं० / No. 31026/92/2020-Policy  
भारत सरकार / Government of India  
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers  
औषध विभाग / Department of Pharmaceuticals

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शास्त्री भवन, नई दिल्ली  
Shastri Bhawan, New Delhi  
Dated the 13<sup>th</sup> August, 2021

**शुद्धिपत्र / परिशिष्ट/CORRIGENDUM / ADDENDUM**

**Subject:- Operational Guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals – reg.**

In continuation to corrigenda of even number dated 30.06.2021 and 22.07.2021 issued by this Department on the above-mentioned subject, the undersigned is directed to convey the following corrigendum/addendum w.r.t. the operational guidelines of the PLI Scheme for Pharmaceuticals:

2. Corrigendum/Addendum dated 22<sup>nd</sup> July, 2021 stands withdrawn.
3. The revised **clause 2.6** shall be read as follows:

**Application Window:** Time period allowed for filing of applications. The application window shall be from 2<sup>nd</sup> June, 2021 to 31<sup>st</sup> August, 2021 (inclusive).

4. A **new sub-clause 4.6.4** under existing Clause 4.6 is added as follows:

4.6.4. Only one applicant, on behalf of its Group Companies (as defined in Clause No. 2.13), shall be eligible for selection under the Scheme. The applicant and its Group Companies where the eligible products get manufactured will be considered collectively for the purpose of ascertaining Threshold/Committed Investments, Threshold/Incremental sales and Incentives under the scheme.

5. The **revised clause 4.1** shall read as follows:

4.1 The selection of applicants in each group (except *invitro* Diagnostic medical devices) will be governed by following parameters:

Sr. No.	Group	Selection parameter	Weightage
1	A / B	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/DMF/CEP, as the case may be, of applicant/ group company from either USFDA/ EDQM/ EMA/ Swissmedic/ UK MHRA/ PDMA/ Health Canada/ TGA/ ANVISA / Regulatory agency of any country which is a member of PICS / Number of WHO-PQ pharmaceutical products 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%
2	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/DMF/CEP, as the case may be, of applicant/ group company from either USFDA/ EDQM/ EMA/ Swissmedic/ UK MHRA/ PDMA/ Health Canada/ TGA/ ANVISA / Regulatory agency of any country which is a member of PICS / Number of WHO-PQ pharmaceutical products as on 01.04.2021	30%
		GMR from pharmaceutical goods in FY 2019-2020	40%
3	C (MSME)	Number of manufacturing plants in India owned by applicant/group company and approved by either USFDA/ EDQM/ EMA/ UK MHRA/ PMDA/ Health Canada/ TGA/ ANVISA/ Regulatory agency of any country which is a member of PICS 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%

**Note 1:** For an applicant manufacturing special empty capsules like HPMC, Pullulan, enteric etc. or complex excipients, the NDA/ANDA containing details (name of manufacturer/address of the plant) of special empty capsule/ complex excipient manufactured by the applicant will also be counted for such an applicant.

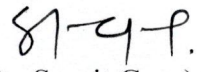
**Note 2:** As per above mentioned changes in clause 4.1, there will be corresponding changes in the Appendix K and Appendix I of the Operational Guidelines of the scheme.

6. The revised table in clause 7.2.3 of the Operational Guidelines, shall read as follows:

(Figures are in Rs crore)

Name of Group	Incentive Ceiling	Ceiling of Additional Incentive, if any	Total Incentive Ceiling
Group A	1000	200	1200
Group B	250	50	300
Group C	50	10	60
Group C (MSME)	Committed Investment or Rs 50 crore, whichever is minimum	20% of Committed Investment or Rs 10 crore, whichever is minimum	120% of Committed investment or Rs 60 crore, whichever is minimum

7. This issues with the approval of the Competent Authority.

  
(Dr. Sumit Garg)  
Deputy Secretary  
Tel- 23389840

To

1. NIC, Department of Pharmaceuticals with the request to upload the same on the website of the Department.
2. Shri. Ravi Tyagi, CGM, SIDBI (PMA)
3. Members of the Technical Committee
4. All Pharmaceutical/IVD associations
5. PS to Minister, Chemicals and Fertilizers
6. PS to MoS, Chemicals and Fertilizers
7. Invest India