

F.No.31026/92/2020-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated 10th July, 2021

CORRIGENDUM / ADDENDUM

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

The undersigned is directed to refer to the above-mentioned subject and state that the contents at table under clause 4.1 and Appendix I & K (wherever applicable) of the operational guidelines may be read as under:

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 /BfArM/ UK MHRA / PMDA / Health Canada / TGA/ANVISA 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 /BfArM/ UK MHRA / PMDA / Health Canada / TGA/ANVISA 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 USFDA / EDQM/ EMA /BfArM/ UK MHRA / PMDA / Health Canada / TGA/ANVISA 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%

(Venkat Hariharan)
Deputy Director

To

1. NIC, Department of Pharmaceuticals with a request to upload the same on the website.
2. Shri Ravi Tyagi, CGM SIDBI(PMA)

3. Members of the Technical Committee
4. All Pharmaceutical/IVD Industry associations
5. PS to MCF (Chemicals and Fertilizers)
6. PS to MoS (Chemicals and Fertilizers)
7. Invest India.