Frequently Asked Questions- PLI Scheme for Pharmaceuticals- 2nd Set

INDEX

Disclaimer: The FAQs and their replies have been made for ease of understanding of the Operational Guidelines of the scheme dated 1st June 2021, read with Corrigenda dated 30th June 2021 and 22nd July 2021. Replies to FAQs reflect the best possible interpretation of the questions asked by the industry members. In case of any difference in any aspect of scheme that emerges post release of the FAQs, the Operational Guidelines dated 1st June 2021, read with Corrigenda dated 30th June 2021 and 22nd July 2021 will prevail over the FAQ.

A. Applicant and Application (including Standard Formats) related FAQs

1.	Separate application by subsidiary- whether the Indian subsidiary of the applicant, can make a separate application on a standalone basis as an independent entity, i.e. not considering the Group Manufacturing Revenue of INR 5,000 of the applicant entity and considering its standalone revenue, thereby qualifying under Group C of the guidelines?
	Only one applicant can apply from the entire group under the scheme.
2.	Is there a concept of co-applicant and Can a Indian subsidiary of the applicant be clubbed for the purpose of computing projected investment and sales. Based on the existing PLI operational guidelines released by the DoP, we understand that an applicant has to apply on the prescribed portal and file the prescribed form. In this regard, a clarity is sought whether an applicant here would have to be restricted at an entity level or it can be clubbed with Indian subsidiaries as well. This is more so from the perspective of computing the investment limits, turnover limits and growth criteria. A clarity with respect to same is requested.
	Co-applicants are not allowed under this PLI Scheme. Only one applicant can apply from the entire group under the scheme. Further, as per the operational guidelines, minimum cumulative investment, threshold/ incremental sales criteria have to be met by the applicant and its group companies.
3.	Auditor Certificate for Document Nos. D2, D5, D11 to D18 - total 10 Nos. - As per format, we should get the certificate from Statutory Auditor for all 10 points mentioned above. As per the guidelines 6.1.5, The heads of investment, based on which eligibility is being determined, should be capitalized in the books of accounts of the applicant as certified by the Statutory Auditor or Independent Chartered Accountant, whichever is applicable, except the eligible investments w.r.t. expenditure on R&D, product registration which may be in the nature of capital/ revenue expenditure where such is certified by the Statutory Auditor/ ICA. Shall we get the Auditor Certificate for all the above 10 document numbers from Independent Chartered Accountant instead of Statutory Auditor.
	Please refer to the revised documents uploaded on the Scheme Portal. As per the operational guidelines, information/ data in the indicative formats shall be certified by the Statutory Auditors, wherever mentioned as such.
4.	As per the ICAI guidelines format of certificate for special purposes is given in appendix 2 of Guidance note-2016 (refer page no 60). Our auditor has expressed some concerns over standard format prescribed by DoP. Kindly suggest whether Format as per ICAI guidelines are acceptable.
	The formats have been developed in line with the scheme guidelines and an applicant shall provide information as per the indicative formats prescribed under the scheme. Further, some relaxations have been provided in the revised formats issued on the Scheme Portal.
5.	Format D8 and Format D9 which is required to be submitted along with the application, are required to be signed by of Managing Director/ Managing Partner/ Proprietor. In case, the company has not appointed Managing Director, can a person authorised by Board sign the documents?
	In case, the company has not appointed Managing Director, a person duly authorised by the board, vide a board resolution may execute the said documents. Further, the applicant shall upload the certified copy of such board resolution along with the respective documents.

B. Global Manufacturing Revenue (GMR) and Group Company related FAQs

<table>
<tr><td>1.</td><td>Our Company Manufacture both Gelatine and HPMC capsule and Turnover from Gelatine Capsule say for 2019-20 is 70 crores and from HPMC capsule is 1 crores, kindly let us know whether consolidated turnover of Rs. 71 crore will be shown or Rs. 1 crore turnover from HPMC capsule will be shown., as we are applying for under product category serial no. 6, kindly clarify.</td></tr>
<tr><td></td><td>As both the products are pharmaceuticals products, consolidated revenue shall be considered for the purpose of GMR.</td></tr>
<tr><td>2.</td><td>We have two more subsidiary outside India, which are in business of trading of capsule in US and Mexico, so kindly let us know, whether revenue by our Subsidiary will also be included i.e. Revenue on Standalone basis or Consolidated basis will be shown in GMR., kindly also clarify</td></tr>
<tr><td></td><td>As per para 2.12 of the operational guidelines of the scheme, GMR is consolidated global revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices.

Hence, the trading revenue of the group companies shall not be considered while calculating GMR.</td></tr>
<tr><td>3.</td><td>We request you to clarify the following points regarding GROUP company under PLI PHARMACEUTICAL scheme.

Applicant: Company A

Other companies: U, V, W, X, Y AND Z
<table>
<tr><td></td><td></td><td>U</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td></td><td>DIRECT HOLDING OF SHARES BY APPLICANT A in other companies IN %</td><td>0</td><td>10</td><td>20</td><td>49</td><td>85</td><td>100</td></tr>
<tr><td></td><td>SHAREHOLDERS OF applicant company A HOLDING shares in other companies in %</td><td>45</td><td>30</td><td>25</td><td>20</td><td>0</td><td>0</td></tr>
<tr><td></td><td>IN THIS SITUATION WHICH IS A GROUP COMPANY TO APPLICANT COMPANY A UNDER PLI SCHEME</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td></td><td>As per the Para No. 2.13 of the Operational Guidelines, Group Company(ies), as defined in the FDI Policy Circular of 2020, shall mean two or more enterprises which, directly or indirectly, are in a position to:

Exercise twenty-six percent or more of voting rights in other enterprise;

or

Appoint more than fifty percent of members of board of directors in the other enterprise.

Accordingly, the Applicant may be guided by the same.

In the instant case, the companies where applicant A can exercise 26% or more of voting rights or can appoint more than fifty percent of members of board of directors, shall be treated as group companies. From the facts produced here, it may be derived that X, Y, and Z may be treated as group company of A.</td></tr>
<tr><td>4.</td><td>It is humbly prayed to include the revenue and investment carried out for contract manufacturing (by way of Loan Licensing or P2P), for the purpose of computation of following and to issue necessary clarification in this regard by way of FAQs:

Global manufacturing revenue as defined under Clause 2.2 of the Scheme Operational Guidelines, dated 01st June 2021; and

Incremental Sales defined under Para 7.2.5 of the Scheme Operational Guidelines, dated 01st June 2021</td></tr>
</table>

	Eligible investment as defined under Para 2.15 and 6 of the Scheme Operational Guidelines, dated 01st June 2021
	In case the sales of products manufactured under contract manufacturing/ Loan Licensing that are booked as manufacturing revenue in the books of accounts and Statutory Auditor's certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR. Trading revenue shall not be considered for GMR. However, revenue from sale of eligible products produced under contract manufacturing shall not be considered for calculating threshold/ incremental sales. Revenue from sale of eligible products produced under Loan Licensing shall be included while calculating threshold/ incremental sales. Investments made on the eligible plant & machinery [including expenditure on associated infrastructure] subject to capitalization of the expenditure in the books of accounts of the applicant and compliance to the conditions laid down in Para No. 2.15 and 6, are eligible under the scheme and shall be considered while calculating minimum cumulative investment.
5.	Manner of presenting Global Manufacturing Revenue (GMR) in case of a Limited Risk Distributorship (LRD) model for MNCs. Para 2.12 of the operational guidelines mentions GMR should be computed on the basis of Consolidated Global revenues of the applicant and the group companies from the manufacturing of pharmaceutical goods. In relation to the same, clarity is required on following: Whether in computing GMR of the applicant and Group company- margin earned by the group under the LRD model (distributorship model) has to be considered? We have explained the above using a small example and request the PMA to please provide their views for the same.

Sr. No	Scenario	Value of sales
1	Applicant Manufactured pharmaceutical goods and Exported to group company outside India	100
2	The recipient group company adds its own margin under the Limited Risk Distributorship (LRD model)	50
3	The recipient group company sold the pharmaceutical goods so imported from applicant (after adding the margin	150

	Now, since the definition of GMR as per para 2.12 provides computation of GMR as per consolidated global revenues from manufacturing of pharmaceutical goods, clarity is required as to in the above case, for computing GMR, revenue shall be computed as 100 or 150. Hence it is requested to clarify on the same.
	Manufacturing revenue of the applicant i.e. Rs.100 shall be considered for calculation of GMR. As per Para 2.12 of the operational guidelines, GMR means consolidated Global Revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices.
6.	Consideration of Other operating revenue in GMR computation Para 2.12 of the operational guidelines mentions for computing GMR revenue from any other source for instance R&D services, rental incomes etc. shall be excluded. In relation to the same, it is not certain as to what all revenues shall be excluded in order to compute GMR.

	We specifically refer to following sources of revenue, which by virtue of the accounting treatment are typically considered as part of the 'operating income' of the Pharmaceutical manufacturing companies. a. Export incentive (such as MEIS/SEIS scripts etc.) received in relation to manufacturing of pharmaceutical goods b. Sale of machinery (as scrap) if used for manufacturing purpose. c. Sale of ANDA/ formulations d. Government grants received pertaining to manufacturing operations e. Foreign Exchange gain – (received in relation to manufacturing of pharmaceutical goods)
	Export incentive shall not be included for GMR calculation, as only manufacturing revenue of the Applicant/ Group Companies is being considered in the definition of GMR given in clause 2.12 of the Operational Guidelines. Sale of machinery (as scrap) shall not be included for calculating GMR Sale of ANDA/ formulations shall not be included for calculating GMR Government grants received shall not be included for calculating GMR. Foreign Exchange gain shall not be included for calculating GMR.
7.	There are two companies in a group, one with turnover of approx. 400 Crore and another one is MSME entity. Now, if we see the GMR of group it will fall under Group-C but the applicant who is filling application for the eligible products is an MSME entity. In this regard, we would like to confirm whether the company will get the benefit available to MSME applicant or a general applicant under Group-C?
	Grouping of the applicants under the scheme (A/ B/ C) would be based on the GMR as defined in clause 2.12 of the operational guidelines and the applicant would continue to remain in the same group (A/ B/ C) during the entire tenure of the scheme. Once the group of any applicant is decided as above, the applicant will have to comply with necessary parameters (selection parameters as defined in clause 4 and incentive criteria as defined in appendix B) pertaining to that group. Only one applicant from the group can apply under the scheme.
8.	1. We have two limited liability companies, Company A and Company B. Company A owns about 29% shares in Company B. So as per the definition, both Company A and Company B are the same Group Companies. Please Note that individually both are MSME Companies. Even if we add up the fixed assets (as per MSME definition), together, the Group as a whole still enjoys MSME status as of today, as total assets (as stipulated in the MSME definition) are below Rs 50 Cr. Turnover of both Companies together is Rs 210 Cr, including Exports of Rs 115 Cr, in 20-21. Company A does substantial manufacturing in Company B on Loan License basis. 2. We have already filed an application to NCLT for amalgamation of Company A and Company B, in Dec 2020. The file is still pending with NCLT. Hearing date not yet received due to Covid lock-downs. We assume it will take another 6-8 months for the amalgamation process to be completed. Hopefully, by March 2022 it will be an amalgamated Company under Company A. 3. Company B is already proceeding with its expansion cum modernization project with a total investment of about Rs 40-45 Cr. Out of this, an investment of about Rs 12 Cr has been incurred up to March 2020.

	To date, a further investment of Rs 18 Cr is incurred. (from April 2020 till June 2021). So far the entire investment is shown as Capital Work in Progress. Further investment of Rs 10-15 Cr will be completed by March 2022. Thus project investment of Rs 30-35 Cr can be committed at the time of application under PLI 2. Once the project is completed, the total project cost (Rs 40-45 Cr) will be capitalized and depreciation will be claimed against it. 4. Company A is also setting up a Green Field project on its own of about Rs 125 Cr. The project investment will be spread over the next 2-3 years. In the current year i.e. year 21-22, building construction will start and investment maybe about 10-15% of project cost (from October to March). Major (60-65%) investment will be in the year 2022-23. Balance may spill over to the year 2023-24. Thus in the case of this Green field project, in the first project year (2021-22), the minimum investment target of 20% as stipulated in PLI 2 will not be met. Kindly advise how to present this at the time of application and whether it will be considered as an eligible investment under PLI 2. 5. Since both Company A and Company B are Group companies, in the process of amalgamation, should we move the PLI 2 application of two projects together in one single application or should we file two separate applications? 6. Can the eligible products currently manufactured by Company A in Company B on Loan License basis be considered for incentive? (Prior to amalgamation! Post amalgamation it will be one entity only.)
	The bank guarantee shall be invoked in case the threshold investment of FY 2021-22 is not achieved. As on date of application, the applicant has to apply under the scheme in its current form. Only one applicant is allowed from a group. Further, cases of merger/ demergers are not events of normal course of business. Hence, such specific cases may be treated on case-to-case basis subsequent to the event which would depend upon the approval by DoP and compliance of conditions stipulated by the DoP on the case specific approval. Revenue from sale of eligible products produced under loan licensing manufacturing by applicant will be considered for calculating GMR, threshold/ incremental sales.
9.	We understand that a group has total three entities in India - two entities BPPL and BACPL are engaged in manufacturing of pharmaceuticals in India and one entity BFRC is a Section 25 non-profit R&D Company with no shareholders and involved in Research and Development activity in India. Basis the details shared with us, we understand that the details of shareholding and Directors in each of the above Company are as follows:

Name	**BPPL**		**BACPL**		**BFRC**
	Percent of shareholding	**Director**	**Percent of shareholding**	**Director**	**Director**
A	30.30%	Yes	29.70%	Yes	Yes
B	10.10%	No	5.40%	No	No
C	34.60%	Yes	24.70%	No	Yes
D	25.00%	No	19.70%	Yes	Yes
Others	0.00%	-	20.50%	No	-
Total	**100.00%**		**100.00%**		

	Given the above details of shareholding and common Directors, we understand that the company desires to understand whether BACPL and BFRC would qualify as 'Group Companies' for BPPL (Applicant company) for applying under the Pharma PLI 2.0 scheme, in the context of definition of 'Group company' as provided under para 2.13 of the Operational Guidelines for the PLI scheme for Pharmaceuticals dated 1 June 2021.
	Group Company(ies), as defined in the FDI Policy Circular of 2020, shall mean two or more enterprises which, directly or indirectly, are in a position to: Exercise twenty-six percent or more of voting rights in other enterprise; or Appoint more than fifty percent of members of board of directors in the other enterprise. If the companies are not in position to Exercise twenty-six percent or more of voting rights in other enterprise; or Appoint more than fifty percent of members of board of directors in the other enterprise, they cannot be termed as group companies under the PLI scheme.
10.	As per 2.12, Gross Manufacturing Revenue means Consolidated Global Revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices. We wished to seek clarification on following situations: Where Group Company (A) of applicant sells manufactured raw materials to another group company (B) of applicant, who uses the said raw materials to manufacture final product and sells to end customer, then for the purpose of GMR, the inter group company sales from A to B needs to be deducted otherwise it would lead to double counting of sales in GMR. Please clarify.
	Yes. In the instant case, the sales from A to B needs to be deducted while calculating the GMR, so as to avoid the double counting. All transactions by the selected applicant with Related Parties will be subject to provisions of relevant statutes and Accounting Standards - 18 and corresponding Ind-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and/ or eligible committed investment.
11.	As per 2.12, Gross Manufacturing Revenue means Consolidated Global Revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices. In case, pharma goods manufactured by Applicant (A) are sold to the Group Company (B) and in-turn, the Group Company (B) sells the goods to the end customer, then for the purpose of Global Manufacturing Revenue (GMR), we understand that sale from A to B shall be counted (as manufacturing revenue) and sale from B to customer shall not be counted (since it is traded revenue)
	Applicant's interpretation is correct. Trading revenue shall not be considered while calculating the GMR.
12.	In a situation where Applicant (A) has only 30% voting rights in one of the Group Company (B), whether entire manufacturing revenue of B needs to be included for computation of GMR or only 30% revenue (being proportionate to voting rights) of B needs to be included in GMR?
	For the purpose of GMR calculation, the entire pharmaceutical manufacturing revenue of the group company (as defined in Clause No. 2.13) shall be considered irrespective of voting rights.
13.	Our Query and understanding on GMR reporting period – For determining the GMR, the period stated is Financial Year (FY) 2019-20. It is understood that the Indian companies including Gland prepare their Financial Statement (FS) on FY concept i.e. from 1 April to 31 March. However, in several Foreign companies including Shanghai Pharma & Fosun Singapore FS are prepared based on Calendar Year (CY) concept i.e. from 1 January to 31 December.

	In such a case, how Gland would consolidate the revenue of Fosun Singapore and Shanghai Pharma which follow CY period for the certification. Will it be appropriate to consider the CY revenue & other data of Fosun Singapore and Shanghai Pharma for the purpose of consolidation with Gland, keeping in mind the limited time given to file the application?
	No. For such foreign companies, where financial years are different than as followed in India, manufacturing revenue for the period April 2019 to March 2020 shall have to be considered while calculating GMR.
14.	Whether income from loan licensing (job work) undertaken for a Company where the invoice is issued for sale of services viz. Conversion charges, can be included for computation of Global Manufacturing Revenue? We understand as per the guidelines, "manufacturing shall mean processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use and the term "manufacturer" shall be construed accordingly" and thus, the work done by us sits well within this definition and thus should be considered as a part of "Global Manufacturing Revenue".
	No. As the revenue is coming from providing services and invoice is issued for sale of services, the same shall not be considered for GMR
15.	We have a profit share agreement with our sole selling distributors in India and our related entities located outside India. As per the said the agreement, the goods manufactured by us are sold on a cost-plus margin model to the distributors / related parties which are in turn sold by them to their customers after adding their commission. In a few cases, the profits earned by the distributor/ related parties are later shared with us on a periodic basis as per the terms of the agreement which is added to "Sale of Goods" in our books of accounts. Whether such profit-sharing income should be included for computation of Global Manufacturing Revenue?
	No As the profit share is not construed to be manufacturing, the same shall not be considered towards GMR.
16.	We recover charges from customers towards expiry and write off of excess stock of raw material procured due to the issue of minimum quantity procurement of such raw materials in the market. Whether such amount recovered from customers can be included for computation of Global Manufacturing Revenue?
	No. As recovery of charge are not construed to be manufacturing, the same shall not be considered towards GMR.
17.	Whether recovery of testing charges for testing before sale to customers (including contract manufacturing sales) can be included in Global Manufacturing Revenue? Please note, such test are mandatorily required to be undertaken without which the goods would not be accepted by the customers.
	No. As recovery of testing charge are not construed to be manufacturing, the same shall not be considered towards GMR.

C. Eligibility for submission of Application related FAQs

1.	We would like to understand from your good office, whether the company having the license from CDSCO/ SLA to manufacture and sell the IVD devices can apply for PLI even to the extent of manufacturing carried out by the contract/ third party manufacturers, who does not have any specific license from CDSCO/ SLA to manufacture In-vitro Diagnostic devices?
	In case the sales of products manufactured under contract manufacturing is booked as manufacturing revenue in the books of accounts and Statutory Auditor's certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR. However, revenue from sale of eligible products produced under contract manufacturing shall not be considered for calculating threshold/ incremental sales at the time of claim of incentives, as per Para No. 2.16 of the Operational Guidelines. As per Para 4.2 of Operational Guidelines, the selection of applicants for in vitro diagnostic medical devices will be governed by one of the parameters viz., 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.
2.	We seek your direction/confirmation for making an application under PLI 2.0 Scheme It is important to mention that though we are in Veterinary space, the regulatory framework is equally applicable similar to Human Pharma. Under the Federal Food, Drug, and Cosmetic Act (the "Act"), the term "drug" means articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles other than food intended to affect the structure or any function of the body of man or other animals. Accordingly, the goods manufactured by us qualify as 'drugs'. As per clause 2.1 of the Scheme, Applicant for the purpose of the Scheme shall be a Company registered in India proposing to manufacture eligible products and making an application for seeking approval under the Scheme. Appendix A (Page 16) of the Scheme covers pharmaceutical goods under three categories as detailed therein. There is no difference between human and veterinary medicines from a regulatory guidelines' perspective. The pharmaceutical sector covers both medicines /drugs for human and veterinary care. The products manufactured by us should be covered under Category 2 as detailed in Appendix A. It is also pertinent to note that Human & Veterinary Regulatory guidelines, review of dossier and site approvals compliance are same for both the segments. • In case of US market – USFDA is the final authority • In case of EU market – EDQM is the final authority • In case of WHO market – WHO Switzerland is the final authority • ICH guideline – International council for Harmonization • VICH Guideline – Veterinary International council for Harmonization In case of Human, new product Innovator Brand approval is NDA (New Drug Application) In case of Animal new product innovator brand approval is NADA (New Animal Drug application) In case of Generic product approval – ANDA (Abbreviated new drug application) In case of Animal generic product approval – ANADA (Abbreviated new animal drug application) Given the above in our view our products in the animal health care space is also covered under the Scheme as there is no exception / carve out made in the said Scheme.

	We request your confirmation so that we can start the process of making application under PLI 2.0 Scheme.
	The applicant may apply under the scheme, provided the products are covered under the Appendix-A of the operational guidelines. Equivalent documents of veterinary drugs as mentioned in the scheme guidelines for human drugs shall be applicable.

D. Eligible Products related FAQs

1.	If an IVD test do not have license (CDSCO/SLA etc.) in FY21-22, and it gets approved after the application submission, will it be eligible for including in the list afterwards.
	Yes, the same may be included in the product mix in the subsequent years. As per clause 7.2.2 of the operational guidelines, the selected applicant shall have the option to change the product mix approved to them not more than 5 times during the tenure of the scheme with the prior approval of the DoP.
2.	Whether the scheme envisages a limit/ cap on the number of eligible products which will be counted for the purpose of computing eligible investment, incremental sales and eventually the proposed incentives?
	There is no limit on number of eligible products for the purpose of computing eligible investment/ incremental sales.
3.	Whether Paracetamol API, would be eligible for benefit in PLI Scheme 2.0, since the same is not covered in the list of 41 products notified in Annexure B of PLI Scheme 1.0?
	As per Appendix A of the operational guidelines, API/ KSM/ DIs are eligible, except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/ DIs/ APIs in India".
4.	• Background As per Para 2.9 of the operational guidelines, dated 01 June 2021, it has been provided that the Eligible Product means a product manufactured in India and included in any of the product categories listed in Appendix A. However, the definition has not clarified on the details to be provided where an eligible product of one product category is used in the manufacturing of multiple eligible products of another category. For instance, if the Company has an API molecule which is eligible as per category 2 of the PLI scheme and the same API is used in number of formulations which gets covered in category 1 of the scheme and, while filing the application, the Company is willing to apply for the said API molecule as a part of this scheme. • Clarification required: While filing PLI application: Whether details of all the formulations, which are manufactured from the respective API molecule, would require to be submitted? OR Whether details of selective formulations, considering the business needs and importance, which are manufactured from the respective API molecule, can be submitted?
	Applicant shall declare name of all the eligible products at the time of application for which it intends to apply. Committed investment/ threshold sales/ Incremental Sales will be in respect of the approved eligible products only. Further, as per Clause No. 7.2.7, in case of in-house consumption of eligible product used for manufacturing a product which is an eligible product under this scheme, then the incentive shall be claimed for only one of the eligible products used/sold subject to sale of the final eligible product.
5.	Kindly also clarify the drugs with separate strengths will be treated as one product or separate products. For instance, we produce both, (i) Erythromycin Tablets 250 mg and (ii) Erythromycin Tablets 500 mg. Will they both be considered 2 different products or only one product?
	The products irrespective of their strength and dosage form are considered one.

6.	Company plans to invest heavily on both API and formulation plant since this scheme is not mentioned specifically for API manufacturers will the investment in formulation manufacturing will be considered under this scheme. In the Operational guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals whether both formulations and API (Active Pharmaceutical Ingredients) will be considered.
	Categorization of the products should be done by the applicant as per the Operational Guidelines as given in Appendix A. If a product is an API/ KSM/ Drug Intermediate, then it will fall under Category 2 only. If a product is a drug formulation, then it can fall under Category1 or Category 3. In case a product falls under both Category-1 and 3, it will be considered under Category-1. Appendix-A of the guidelines may also be referred wherein Category-3 clearly mentions- (Drugs not covered under Category 1 and 2).
7.	While preparing the product list by Applicants whether as mentioned in Appendix A, category 1 as mentioned that a product where Patented drugs or drugs nearing patent expiry will be considered or not. Further in Appendix A, category I of product includes both formulation & API?
	Patented drugs or drugs nearing patent expiry is covered under the category 1, sub category 3. Categorization of the products shall be done as per the Operational Guidelines. If a product is an API/KSM/Drug Intermediate, then it will fall under Category 2 only. If a product is a drug formulation, then it can fall under Category1 or Category 3.
8.	Clarify meaning of Patented drug, does it mean patent applied or granted in a territory? In our view; it would cover only granted patents.
	Yes. Granted patents will only be considered.
9.	We understand that categorisation has to be looked into at the time of PLI application & not at the time of launch of the product. Please confirm our understanding
	Yes. Eligible products shall be categorised at the time of application as per the list given in the appendix A of the operational guidelines. Further, the selected applicant shall have the option to change the product mix approved to them not more than 5 times during the tenure of the scheme with the prior approval of the DoP.
10	This is with respect to the PLI scheme announced for pharmaceutical industry. We are evaluating benefits under the said scheme and wish to apply under "Other drugs as approved", in Category I. We have certain clarifications to be sought in respect of the scheme and have summarized the same in the appended representation letter for your ease of reference. We request your good self to kindly look into the same and provide your valuable inputs to enable us to go ahead with the application.
	There are no drugs approved under this category. Decision for the Other drugs sub-category in both Category 1 and 3 would be taken by DoP, as explained in Appendix A of the Operational guidelines.
11	Since, IVD raw materials is a very critical component for the development of these IVD devices & kits, request to consider the same in either IVD category or any other category as suitable. This will support & promote such companies. It can be included within in vitro diagnostic devices would include any allied/ directly related raw material under the same category (kindly refer Appendix A - Category (III) 3.)? Thanks. Looking forward to you revert.
	The product categories/ subcategories are defined in the Appendix A of the scheme guidelines. Further, as per the clarifications provided by technical committee, only IVDs are included in the scheme.

12	We are engaged in manufacture and sale of Ayurvedic and Unani medicines which are duly approved by Ministry of AYUSH. We are interested in applying under the production linked incentive scheme for pharmaceuticals announced recently. In this respect, we would like to understand if the drugs approved by Ministry of AYUSH are eligible for incentives provided under the said scheme.
	Ayurvedic and Unani medicines are not covered under the scheme.
13	Request you to kindly let us know if this can be taken as a basis to evaluate whether the product would be considered as a complex generic drug or not. Alternatively, kindly issue specific guidance on this matter, which could form a basis to determine the eligibility and help us in filing a comprehensive application under the PLI scheme along with the right set of the eligible products.
	Complex generic drugs include complex active ingredients such as peptides, polymeric compounds; complex formulations such as liposomes; complex route of delivery (e.g. locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions or gels); complex dosage forms such as Transdermal Patch; complex drug-device combination such as autoinjectors

E. Selection Parameters and Ranking related FAQs

1. On a perusal of the Guidelines, it is understood that for an applicant falling under Group C MSME, one of the parameters for selection is the number of manufacturing plants owned by the applicant/ group company in India having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021 or approved by USFDA/ EDQM/ UK MHRA/ PMDA/ Health Canada/ TGA.

   In this regard, we wish to submit that the Company currently has two manufacturing units / plants and one of them is already USFDA approved and in possession of WHO-GMP compliance certification as on 01 April 2021. However, with respect to the second unit, the said certification is pending as on date and we are seeking a specific clarity w.r.t. the same.

   For the second unit, while the inspection for WHO-GMP certification is already carried out, we are yet to receive the certification from the licensing authority. We have mentioned here-in-below a chronology of the events that have happened in respect of the second unit:

S. No.	Date	Event
1	07 January 2021 & 08 January 2021	WHO-GMP inspection/ audit was carried out.
2	21 January 2021	Audit observations report was received.
3	27 January 2021	Pursuant to the issuance of the audit observations report, an audit compliance report was duly submitted by the Company.
4	23 March 2021	Subsequently, after a duration of 2 months, the Joint Director, Guntur had raised queries and also sought certain information from the Company post audit/ inspection.
5	30 March 2021 & 22 April 2021	In respect of the queries raised by Joint Director, the Company responded with partial information on 30 March 2021 and could respond with balance information by 22 April 2021 due to the Covid-19 pandemic since most of the staff were on sick leave.
6	-	No further update on this matter. Company is awaiting certification from the licensing authority.

   In view of the above, it can be seen that the second set of queries were raised by the authorities 2 months post completion of audit inspection and submission of compliance report. Post which, the Company has complied with all the requirements of the authorities by co-ordinating and furnishing the requisite documents/ details, even in this pandemic situation. Further, time taken by the Company to furnish the required information/ data was after taking into consideration the fact that most of the employees were on sick leave and hence, the required documents/ information could not be collated any sooner. Nevertheless, the Company has furnished all the required information/ data sought by the authorities on 23 March 2021.

   Further, we understand that due to pandemic, the actions on the part of the authorities may have been impacted which has resulted into a delay in obtaining the WHO-GMP certification. Since the criteria for selection requires the applicant to have certain number of certified units as on 1 April 2021, we request your goodself to kindly let us know whether any consideration / benefit in this regard can be given to us.

   Only approved WHO-GMP certification shall be considered.

   As per the parameters for selection of applicants mentioned in the Operational Guidelines [Para No.4], MSME Applicants having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021 would be considered.

2.	In clause, 4.2, where the number of manufacturing plants of a company will be considered as the evaluation criteria. However, it is not clear, if X company has one plant with a big area (say 25000 sq ft) and the company Y has 5 plants with a total area of 10000 sq ft, then how will the companies be evaluated? Any other parameters, viz. location, products, capacity etc will considered for counting manufacturing plants.
	As per the operational guidelines, selection of applicants for in vitro diagnostic medical devices will be governed by the parameters given in Clause No. 4.2. Hence, number of manufacturing plant shall be considered as a selection parameter. Location/ products/ capacity etc. shall not be considered.
3.	Complete list of investments to be included/ excluded while computing Gross Manufacturing Investment (GMI) is not notified. Para 2.22 of the operational guidelines provides that for the purpose of selection of the applicant, GMI will include Gross capital investment in pharmaceutical and invitro diagnostic medical device manufacturing facility alongwith capital investment in R&D facilities. Further, it also mentions the list of investments in corporate offices, sales offices, residential complex etc. shall be excluded. However, on perusal of the above, it is ambiguous as to which type of investments are actually to be included while computing the GMI. We specifically seek clarification with respect to the below listed investments made by an applicant. • Investments in CWIP (part of the manufacturing operations) are to be included or not. • Investment in Vehicles (used for transporting raw materials) are to be included or not? • Investment made in Land or property (on which factory is built) to be included or not? • Investment in Intangibles (Computer Software, Product development/Brands) to be included or not? Further, we also request the PMA and DoP to please provide a definition of GMI which specifically covers or links the manner of computing the GMI.
	As per para no. 2.22 of the operational guidelines, GMI will include gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities. CWIP in a given year shall not be a part of GMI. Investment should be capitalized in the books of account of the applicant during the investment period. Investment in vehicles shall not be included while calculating GMI. Investment in land/ property on which the manufacturing facility is built may be included while calculating GMI. However, Investment in corporate offices, sales offices, residential complex etc. will not be included for the purpose of arriving at the GMI. Investment in intangibles shall not be included. GMI has been defined in Clause no. 2.22 of the operational guidelines.
4.	Whether in computing R&D Expenditure, as a % of GMR, R&D incurred by overseas group companies in abroad should be considered? We refer to para 4.1 of the operational guidelines where an applicant is required to compute R&D Expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020. In this regard, we seek clarity on following: • Whether R&D Expenditure incurred by overseas group companies outside India should be considered for above computation?

	• Whether R&D Expenditure incurred by an applicant outside India for a product development outside India should be considered for above computation? • Whether there is a requirement to prove nexus of R&D Expenditure with the eligible products under the scheme? •Whether sub-contracting of R&D Activity by an overseas group Company in India should be considered for above computation?
	Yes, in respect to selection criteria-3 (for Group A/ B applicants) R&D expenditure of applicant/group company as a % of GMR shall include R&D expenditure incurred by the applicant/ group companies in India and overseas. Yes, R&D Expenditure incurred by an applicant outside India for a product development outside India shall be considered for above computation Yes, R&D expenditure shall be incurred towards approved eligible products. For sub-contracting, if the same has been booked as R&D expenses by the applicant/ group, the same shall be considered.
5.	As regards the Gross Manufacturing Investment in last 10 years for the purpose of selection parameters, whether such Investment acquired/received by the Amalgamated company on amalgamation/merger of Amalgamating company should be considered or not? For example, X Ltd= Applicant; Y Ltd=Amalgamating Company; Y Ltd merged into X Ltd on 1.4.2014 and therefore the Plant & Machinery of Y Ltd was added to the Plant & Machinery of X Ltd on 1.4.2014. Whether this addition of this Plant & Machinery of Y Ltd shall also be considered as GMI by Applicant company.?
	In case of acquisition by the Applicant, the net asset value of acquired manufacturing facilities in the books of the applicant based on the acquisition cost for the manufacturing facilities (as in Para No.2.22) at the time of acquisition as certified by the statutory auditor shall be included for the purpose of calculation of GMI.
6.	PLI Scheme 2.0 mentions that APIs not covered in list of 41 products of PLI Scheme 1.0 would be eligible for the incentive in current scheme. 41 products of PLI Scheme 1.0 are covered in Annexure B. Hence, whether benefit would be eligible under PLI Scheme 2.0, if the API is not mentioned in list of 41 products of Annexure B and covered in Annexure A of PLI Scheme 1.0?
	Yes As per Appendix A of the operational guidelines, API/ KSM/ DIs are eligible, except for the 41 eligible products already covered under the “Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/ DIs/ APIs in India”.
7.	We refer to the evaluation criteria applicable to Group A/ B applicants, basis which 30 percent weightage would be given to ‘Number of ANDA/ NDA of applicant/ group company from either USFDA/ EDQM/ UK MHRA/ PMDA/ Health Canada/ TGA as on 1 April 2021’. The abovementioned approvals, however, are not applicable and required for manufacturing of HPMC Capsules. The company supplies empty capsules to the pharmaceutical companies, which are required to obtain such licences. As of now the Company supplies capsules for around 190 ANDAs product which are registered by various pharma companies. If the aforementioned evaluation criteria is applied to the capsule manufacturer, then the same would not offer a fair evaluation to the capsule manufacturers. This further creates a conflict in the policy as the product i.e. Special empty capsules, including HPMC capsules, are specifically covered in the policy, whereas the evaluation criteria do not give a due consideration to the product.

	Given the above, if the requirement of Number of NDA/ ANDA etc. is not relaxed for the capsule manufacturers, then the segment would not gain sufficient weightage for selection in the scheme and would end up losing the benefit under the scheme. In view of the above, the Company requests the Ministry of Pharmaceuticals to relax the evaluation condition of 30% weightage accorded to ANDA/ NDA approvals for capsule manufacturers, and offer a level playing field to the segment.
	For applicants manufacturing only special empty capsules like HPMC, pullulan, enteric Etc or complex excipients and not drugs, and therefore for which the selection parameter of number of ANDA/ NDA/ DMF/ CEP is not relevant, the weightage for other relevant criteria will be increased pro-rata so that such applicants are not placed at a disadvantage. Weightage shall be assigned as following. For Group A/ B (i) Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20 – 43% (ii) R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020 – 57% For Group C (Non-MSME) (i) Gross manufacturing investment of applicant/ group company in India in 10 years during FY 2010-11 to FY 2019-20 – 43% (ii) GMR from pharmaceutical goods in FY 2019-2020 – 57% In case the applicant is an MSME, then the selection criteria shall be governed by Para No. 4.1 and the corrigenda of the operational guidelines.
8.	What will be the marking for USFDA approved plant or WHO-GMP approved plant. Whether both the marking for USFDA approved Plant & WHO-GMP will be same.
	Marking in both the case shall be same. The marking will strictly be done as per the selection parameters given in the Clause No. 4 and Appendix J of the of the scheme guidelines.
9.	As per the guidelines, Gross Manufacturing Investment (GMI) will include gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities. For the purpose of computing GMI as per para 2.2, Please clarify as to what all should be included in 'gross capital investment'. Whether the definition of Eligible Investment as mentioned in para 2.15 of the guidance can be taken as basis to determine 'gross capital investment' for the purpose of GMI computation Whether investment done in land and building for the purpose of set up or modification of the manufacturing facility of pharma products, shall be included in GMI? whether intangibles such as IPR, etc. acquired and capitalized would be included in GMI
	Investment done in land and building in respect to the manufacturing facilities only of pharmaceutical products, may be included in the computation of GMI. Intangibles such as IPR etc. shall not be considered in the computation of GMI.

F. Eligible Investment related FAQs

1.	We request you to clarify regarding applicant in this scheme. Our doubt is an applicant is a single entity or group of entities for investment of Rs. 1000 cr, 250 cr, 50cr and claiming incentive on incremental sales by GROUP A, GROUP B and GROUP C respectively.
	Only one applicant can apply from the entire group under the scheme.
2.	If an applicant Company falls in category C-MSME and Joint Venture/ Consortium Is formed with Group Company to fulfils the eligibility criteria for an Applicant Company, is this MSME applicant company is required to commit investment of at least 50 crores under C-category as for eligibility group company data is being filled up for MSME applicant company or Can It be less than 50 crores also under C-MSME category.
	The applicant may please note that the grouping of the applicants will be done as per the GMR criteria mentioned in the Clause No.2.2 of the operational guidelines. Further, you may please note that the GMR of the Applicant and its Group Companies, is an eligibility/ selection parameter. The application would require a Statutory auditor certificate in respect of the GMR of the applicant and all its group companies. Further, the scheme does not have any minimum investment criteria for the MSME applicants. MSME applicants have to declare their committed investment in the application form and they have to meet the year wise minimum cumulative investment as per appendix B of the operational guidelines.
3.	R&D expenditure - Whether R&D expenditure (revenue expenditure) incurred in the USA by one of the foreign subsidiaries of applicant and cross charged to Indian applicant entity would be counted towards committed investment, for the PLI Scheme.
	No. R&D expenditure shall include expenditure on R&D and product development including clinical trial costs in India only.
4.	Inclusion of details with respect to subsidiary - Whether investment made by applicant entity in its subsidiary would be counted towards total committed investment, considering the fact that applicant entity would fund this investment by way of equity/debt contribution to its subsidiary? If yes, whether sales of such Indian subsidiary can be included by applicant entity as part of its sales while providing incremental sales figures for PLI purposes and therefore, incentive be provided on the total incremental sales (i.e. of both applicant and its Indian subsidiary)?
	Investments made on the eligible plant & machinery [including expenditure on associated infrastructure] subject to capitalization of the expenditure in the books of accounts of the applicant and compliance to the conditions laid down in Para No. 2.15 and 6, are eligible under the scheme and shall be considered while calculating minimum cumulative investment. As per the operational guidelines, minimum cumulative investment, threshold/ incremental sales criteria have to be met by the applicant and its group companies.
5.	In clause, 2.15.3, expenditure for transfer of technology, will the expenditure for technology transfer from out of India be eligible?
	Yes. As per the operational guidelines, expenditure incurred on Transfer of Technology will be covered under eligible investments subject to the compliance of Para No.2.15.3. The expenditure is also to be capitalized in the books of accounts of the applicant and to be certified by the statutory auditor.
6.	What if any applicant is not able to fulfil their committed investment over the 5 years period clauses as required under clause 4.1-3C (Pg. 4 & 5) read with clause 7.1.4 (Pg. 8), in case where any applicant have inflated committed investment to achieve higher marks under selection process?

	In case the applicant does not meet the threshold investment of FY 2021-22, then the bank guarantee shall be invoked. Further, If the Applicant fails to achieve minimum cumulative investment in any year, then the Applicant will be ineligible for receiving the incentive for that particular year.
7.	Whether certain investments under 'Eligible investment' only to be mapped at eligible pharma goods (under the PLI) or can be used for Other Pharma goods Associated Utilities– Whether can be used for both eligible and not eligible pharma products (under the PLI scheme)? • Para 2.15 of the operational guidelines mentions eligible investments means expenses incurred in relation to eligible products. Further para 2.15.1 provides for expenditure incurred on New Plant, Machinery, Equipment and Associated Utilities which shall be considered as eligible investment. Further, para 6 of the operational guidelines provides for General terms and conditions w.r.t eligible investment wherein vide para 6.2 further it has been clarified that the Plant, Machinery and Equipment can be used for manufacturing of eligible pharma goods and other goods as well. • However, the said para along with other paras of the operational guidelines are silent on the usage of 'associated utilities' as to whether the same shall be used only for eligible products or can be used for non-eligible products as well. We request a specific clarity in this regard from the PMA and DoP. Research and Development – Whether expenditure has to be for eligible pharma products (under the PLI scheme) only? • Para 2.15 of the operational guidelines mentions eligible investments means expenses incurred in relation to eligible products. Further para 2.15.2 provides for expenditure incurred on R&D and clinical trial cost in India shall be considered as eligible investment. Further, para 6.3 of the guidelines also mentions that such expenditure shall be considered for determining eligible Investment. • However, the said para alongwith other paras of the scheme are silent on whether the said R&D expenditure can be incurred only for eligible products or can be incurred for non-eligible products as well. We request a specific clarity in this regard from the PMA and DoP. Associated Infrastructure – Whether can be used for both eligible and not eligible pharma products (under the PLI scheme)? • Para 2.15.5 of the operational guidelines mentions that eligible investment shall include expenditure on Building and associated infrastructure (upto 20% of the investment in new plant and machinery). W.r.t building it has been clarified that building where new P&M is installed shall be considered for eligible investment and further, vide para 6.2 further it has been clarified that the Plant, Machinery and Equipment can be used for manufacturing of eligible pharma goods and other goods as well. • However, the guidelines are silent on 'associated infrastructure' as to the same shall be used only for the eligible products or can be used for non-eligible products as well. We request a specific clarity in this regard from the PMA and DoP.
	As per Para 6.2.3. The Plant, Machinery and Equipment of the Project approved under the scheme shall be used in regular course for manufacturing of goods under the eligible product categories. This does not preclude the usage of such machinery for manufacturing of other pharmaceutical goods. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme. Further, the applicant may please note that, the relation between Investment and Incremental Sale of the Eligible Product would be in terms of the Operational Guidelines. Yes, Associated infrastructure shall also be for regular usage towards the the eligible product categories. This does not preclude its usage in respect to other pharmaceutical goods. The applicant must submit a

	declaration about usage of associated infrastructure for each year during the period that such applicant is claiming incentive under the Scheme.
8.	Whether Investment in Plant & Machinery for manufacture of API to be consumed captive in manufacturing of eligible formulation/dosage product would qualify as Investment for the purpose of scheme or not?
	If the Plant & Machinery is being used in regular course of action for making API, which is being consumed for making the eligible product under the scheme, it could be considered as eligible investment under the Scheme.
9.	Whether the Investment in Plant & Machinery for manufacture of API as mentioned in Query 1 above is consumed captive in manufacturing of both eligible and non-eligible formulation/dosage products would also qualify as Investment for the purpose of scheme or not? (Note: API investment would not be viable in the absence of scale and hence the investment would be to create a multipurpose API production line).
	If the Plant & Machinery is being used in regular course of action for making API, which is being consumed for making the eligible product under the scheme, it could be considered as eligible investment under the Scheme.
10	• Background As per Para 2.15 of the operational guidelines, dated 01 June 2021, it has been provided that the Eligible Investment means expenses incurred in relation to Eligible Product. However, more clarity is needed on the eligibility of investment done in manufacture of ancillary products, which are essential for the consumption of the eligible products. For instance, the Company is producing a formulation (eligible product) for sale and wishes to apply for incentives on production of the said formulation. Additionally, the Company is also planning to invest in manufacture of medical grade device(s) that would be necessarily consumed and sold, along with the formulation (i.e. main product). • Clarification required While filing PLI application: Whether the investment done on the manufacturing of the respective device that is being sold with the formulation (eligible product) would be considered as eligible investment for the purpose of PLI application?
	As per para 2.15 of the operational guidelines, eligible investment means expenses incurred in relation to Eligible Product. In the instant case, if the medical grade device which is planned to be sold with the eligible product (main product as mentioned in the background) is eligible as per the Appendix B of the operational guidelines, then investment towards the same will be considered under the scheme.
11	In section 2.15.2 Expenditure incurred for Research and Development (R&D): whether expenses incurred in R&D and DMF expenditure will be considered for Applicants.
	In case expenditure are towards R&D purpose, incurred in India during the period 01.04.2020 to 31.03.2026 and the same is booked under the R&D head in the books of accounts of the applicant and certified by the statutory auditor, the same shall be considered under eligible investment.
12	Our expense as Applicant as MSME in group C for new plant in Dahej, Gujarat where expense for year 2020 is 10 cr, year 2021 is 10 cr, year 2022 is 3.5 cr, year 2023 is 3.5 cr, year 2024 is 3.5 cr. Total cost of our new project as MSME is 30 cr. Will you consider our investment as Applicant as mentioned above instead of 20% each year suggested by you in the circular?
	Eligible investments may be made by the applicant as per the project requirements, may be in one year or spread into multiple years. However, to be eligible for incentive, the applicant should meet year wise minimum cumulative investment between FY 2021-22 to FY 2025-26 as given in the Appendix B, subject to other eligibility for incentive.

13	Whether a Parent Company can apply for the scheme, and later on set-up a subsidiary (upon selection) for making investment under the scheme and claim the incentives.
	Yes. The selected applicant may make investment through a group company set up later under the scheme for claiming the incentives.
14	For eligibility of R&D expenditure, whether it is mandatory that the R&D activity should be in relation to pharma products only
	Yes R&D expenditure shall include expenditure on R&D and product development including clinical trial costs in India only, for approved eligible pharmaceutical products.
15	Clause 2.15 refers to Eligible Investment under the Scheme which is broad and encompasses a variety of investments. Clause 2.15.1 covers expenditure incurrent on new plant, machinery, equipment and associated utilities. The coverage therein is wide enough to cover all investments related to manufacturing of eligible products. In this context, we seek clarity on the investment related to insulation and cladding required for machinery/ equipment which needs to be mandatorily required for the maintenance of our machines / equipment. Please find attached a technical note on the insulation/ cladding process. In a continuous batch processing manufacturing set up like ours, it is very important to have all the equipment and utilities well insulated and cladded for better productivity and reduced energy consumption. Therefore, we request your good office for clarity on the inclusion of the cost of the change in Insulation and Cladding material as part of Eligible investments under the said Scheme.
	Yes, insulation and cladding required for machinery may be covered under the scheme provided capitalised in the Applicants book of accounts during the scheme period and subject to compliance of para no. 2.15 and para No. 6 of the Operational Guidelines.
16	Whether the R&D expenditure incurred in relation to all the eligible products which are included in the application filed under PLI scheme would be considered as eligible investment even in case where certain eligible products are not commercialized during the tenure of the scheme. The same could happen due to various reasons such as: (a) R&D of the product is still in progress by the end of the scheme period (b) R&D is completed but the product is yet to be approved by the regulatory authorities (c) R&D is completed and approval from regulatory authorities is received, however the products could not be manufactured / commercialized due to lack of market etc., e.g. Where the Company has applied and received approval for 10 eligible products and could manufacture/commercialize only 8 products during the tenure of the scheme, whether the R&D expenditure incurred by the Company toward the remaining 2 products which are not commercialized be disallowed from the minimum cumulative investment? Our understanding and interpretation: As per clarification issued vide FAQ 6 of claim for incentive (page no 23), it has been clarified that to be eligible for incentives, the applicant has to achieve both the minimum cumulative investment and threshold / incremental sales. As can be seen, the FAQ does not specifically deny R&D expenditure as an eligible investment in the event there is no commercialization. Further, it goes on to state that the eligibility for incentives will occur only in the event applicant achieves both the minimum cumulative investment and the threshold / incremental sales. Accordingly, even if there is no commercialization of certain eligible products during the tenure of the scheme, the R&D expenditure towards such products would still be considered under minimum cumulative investment.
	Yes. applicant's interpretation is correct.

	R&D expenditure towards approved eligible products shall be considered for eligible investments, irrespective of products' commercialization. However, it may be noted that to be eligible for incentive the applicant has to achieve both the minimum cumulative investment and threshold / incremental sales.
17	Whether the minimum cumulative investment criteria can be fulfilled through R&D expenditure alone in a new facility while the criteria of incremental/threshold sales is achieved by manufacturing the products from an existing facility without any new investment in plant and machinery? Our understanding and interpretation: As per clarification provided vide FAQ 33 of eligible investment (page no 15), It has been clarified that Investment may be made in the existing plant or a new location, as per choice of the applicant. It was further clarified that sales of the eligible products would be considered from existing or new setups for the purpose of calculation of incentives. Accordingly, there is no mandate to make an investment in new plant and machinery (or) manufacture the eligible products from new plant and machinery if procured out of minimum cumulative investment.
	Yes, the entire investment may be done from R&D expenditure in relation to approved eligible product(s). For the purpose of threshold/ incremental sales, sales of approved eligible products manufactured at existing facility may be considered.
18	Whether after tax amount will be taken while considering committed investment
	The creditable taxes such as GST, etc. should be excluded. Only non-creditable taxes and duties would be included while calculating committed investments.
19	Computation of R&D Expenditure for the purpose of eligible investment We refer to clause 2.15.2 of the operational guidelines where an applicant is required to compute R&D Expenditure (Capital and Revenue Nature) of applicant for the purpose of calculating eligible investment. We also refer to the related FAQs under the heading Sr. No. G- Eligible Investment (FAQ - 34). Considering the clarifications provided, we seek clarity in respect of the following situations, which in our view have not been answered by the FAQs released by DoP The FAQ 19 of the Eligible investment clarifies that eligible investment in relation to the eligible products only will be considered, with an exception for plant and machinery and equipment. However, from a practical perspective, R&D expenses (revenue expenditure) is difficult to bifurcate between eligible and non-eligible pharma goods. In this backdrop, clarifications on following is requested: • Whether the applicant will be required to scientifically arrive at eligible R&D Expenses by way of apportionment, If yes, what basis should be considered? • Whether the applicant will be required to demonstrate nexus of the R&D expenditure (revenue) with that of sale of eligible pharma products? • Whether R&D related plant, machinery and equipment's which are commonly used for eligible and non-eligible products would be considered as an eligible investment? • Whether R&D related revenue expenditure (eg: salary of R&D staff) which are commonly used for eligible and non-eligible products would be considered as an eligible investment? • Whether the applicants are required to maintain separate records for R&D expenditure incurred for eligible and non-eligible products? • What all documents would be required by the authorities to verify the genuineness of R&D expenditure incurred by the applicant

	With regard to the query, it is clarified that as per Para 2.15 of the Operational Guidelines of the Scheme, eligible investment means expenses incurred [including expenditure incurred for Research and Development (R&D)] in relation to Eligible Product. Accordingly, it is further clarified as under: Yes. R&D Expenditure in relation to eligible product shall only be considered as per the scheme guidelines. The applicant has to keep a record of the R&D costing in respect of eligible products. R&D expenditures as certified by the Statutory Auditor shall be covered under eligible investments. No, there is no requirement of nexus between R&D expenditure and sale. Yes, R&D related plant, machinery and equipment's which are commonly used for eligible and non-eligible products, would be considered as an eligible investment. R&D Expenditure made in relation to only eligible products, may include manpower cost related to R&D in India provided the same has been included under the head R&D Expenditure and certified by the Statutory Auditor as per the specified format. Yes, applicants are required to maintain separate records for R&D expenditure incurred for eligible and non-eligible products. A statement in this regard to be certified by the Statutory Auditor and submitted.
20	We refer to clause 2.15.2 of the operational guidelines where an applicant is required to compute R&D Expenditure (Capital and Revenue Nature) of applicant for the purpose of calculating eligible investment. We also refer to the FAQs from the heading Claim for Incentive (FAQ – 3, 6) and Eligible investment (FAQ – 34). Considering the clarifications provided, we seek clarity in respect of the following situations, which in our view have not been answered by the FAQs released by DoP FAQ 3 under the heading Claim for Incentive clarifies that in case new eligible products are being added in the product mix of the applicant later in the scheme say FY 2023-24, the applicant will be allowed to claim the investment towards P&M or R&D (as defined in clause 2.15 of the operational guidelines) in respect of the newly approved product. This is subject to the approval of the product mix by DoP. In this backdrop, clarification on following is requested: • While the above referred FAQ and FAQ 4 of Eligible Investment related FAQ clarifies that the expenditure in respect of newly added products (to product mix) will be available to the applicant, there is no clarity in which FY such expenditure will be eligible. We request the DoP to clarify on same. • In a situation where the applicant had claimed entire R&D Expenditure incurred in a given FY (say FY 2022-23) and changes its product mix in FY 2024-25 (addition of products), whether the applicant would be required to rework the eligible investment amount pertaining to R&D Expenditure claimed in the previous FY?. This is considering the fact that there could be certain portion of R&D Expenditure pertaining to FY 2022-23 could be attributable (but not quantifiable practically) to newly added products, which have been approved in FY 2024-25 onward. This is an inference-based question of FAQ 3 under the heading Claim for Incentive? • Whether R&D expenditure with respect to a product (not intimated at the time of the application for secrecy or any other reason) and eventually the applicant is not able to launch the product during the tenure of the scheme, would be considered as an eligible investment? • Whether R&D expenditure made towards an eligible and listed product which the applicant is not eventually able to launch or sell during the tenure of the scheme, whether there will be requirement to rework the eligible investment amount claimed in the previous FYs?
	This has already clarified in the previous FAQ dated 01/07/2021. The relevant section of the FAQ is being reproduced: The investment in relation to the product that is approved by DOP in a later stage, shall be

	considered from 01/04/2020. However, for calculation of minimum committed investment, the investment shall be considered for the FY in which DOP's approval is granted. No. When the new product mix is approved, the investment towards the new product mix made on or after 01/04/2020 shall be considered as eligible investment. However, for calculation of minimum committed investment, the investment shall be considered for the FY in which DOP's approval is granted. No. Rework won't be required as clarified by the preceding statement. No. However, if the eligible product is not approved for an applicant, then the investments including the R&D expenses for that product shall not be considered as eligible investment.
21	In context with R & D expenditure, can we also consider the Research & Development expenditure incurred by our subsidiary company of our group companies based in India on Research and Development.
	For the selection parameter, R&D expenditure of applicant and group companies only shall be considered.
22	Whether acquisition of an existing manufacturing set up along with the technical know-how and brand would be considered as eligible investment?
	As per clause 6.1.2 of the Operational guidelines, no second-hand machinery is allowed under the Scheme. The assets (P&M) acquired as part of the acquisition would be used assets and therefore, are inadmissible as eligible investments. Further, intangibles acquired under acquisition shall not be considered for as eligible investment.

G. Threshold/ Incremental Sales related FAQs

1.	Whether the export sales revenue will be taken into consideration separately.
	As per the operational guidelines, the product should be manufactured by the applicant in India. The product may be sold anywhere in India/ abroad.
2.	Stock transfer by Holding Company to subsidiary Company will be included as sales figures for holding company or not.
	If the approved eligible product is manufactured by the applicant and sale of same is booked as revenue of the applicant in the books of account of the applicant and certified by the statutory auditor, the same may be considered for calculation of threshold sales and incremental sale. All transactions by the selected applicant with Related Parties will be subject to provisions of relevant statutes and Accounting Standards – 18 and corresponding Ind-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and/ or eligible committed investment.
3.	In section 7.2.2 whether option to change of Product mix for MSME in group C applicants will be same 50 lakhs limit every year.
	As per Clause No. 7.2.2 of the scheme guidelines, the selected applicant (including the MSMEs) shall have the option to change the product maximum 5 times during the tenure of the Scheme with the prior approval of the DoP. Further, for the purpose of determining eligibility of incentive for first year i.e. FY 2022-23, the threshold sales in FY 2022-23 for eligible products (taken together) has to be greater than Rs.50 Lakh in case of a Group C MSME participant.
4.	How will a patented drug have a turnover of more than Rs. 50.00 lacs (for MSME) in year 2022 - 2023?
	Threshold sales in FY 2022-23 for all eligible products, taken together, to be greater than Rs. 50 lakh in case of a Group C MSME participant.
5.	Suppose in Appendix A, category I of our products on API company sells an API of near expiry of patented product and our formulation company sales the final product on which value will the incentive be calculated?
	As per the operational guidelines, only one applicant from the group can apply under the PLI scheme. Approved eligible products of the applicant and its group companies will be considered for the purpose of eligible investment, threshold / incremental sales.
6.	Whether after tax amount will be taken while considering the net incremental sales and base sales figures. Basically, whether GST will be considered for net incremental sales
	For the purpose of base year sale/ threshold/ incremental sales, the sales figure shall be considered without GST.

H. Claim for Incentive related FAQs

1.	Is this MSME applicant company eligible as an applicant for C-MSME benefits, then whether base year for determining the eligibility of incentive for FY 2022-23, Group Company Turnover for 2019-20 will Be considered or Minimum threshold sales of MSME applicant company will be considered without Taking the incremental sales in MSME applicant company based on Group company sales.
	As per the operational guidelines, minimum cumulative investment, threshold / incremental sales criteria have to be met by the applicant and its group companies.

I. Miscellaneous FAQs

1.	In form no. D-5, Shareholding pattern, it is mentioned April 01, 2021, can Auditors mentioned shareholding pattern as on March 31, 2021 or April 02, 2021 instead of April 01, 2021 (reason: Our RTA provide shareholding pattern upon close of quarter or weekly basis on end of Friday every week or on the date of record date. Since Our Quarter is closed on 31.03.2021, we have shareholding pattern on 31.03.2021 but April 01, 2021 is being Thursday, where RTA is not able to provide however it can provide on April 02, 2021 i.e. Friday.)
	The applicant shall submit the shareholding pattern as on March 31, 2021.
2.	Can we make payment of fees i.e. Rs.10,000/- (MSME applicant) in two to three days advance and then fill the details of fees in Form or it must be paid on the same date of submission of forms.
	The Applicant may pay the non-refundable application fee in advance. The details of the payment may be correctly filled in the section 4 of the application.
3.	Our query is that whether as Applicant has to submit quarterly review report to be submitted and from which year. Appendix F to be submitted after approval or before approval.
	The selected applicants under the scheme have to submit quarterly review reports throughout the tenure of the scheme. The timeline for such submission will be intimated separately.
4.	Based on Point no. 7.2.2 of the Guidelines read with FAQ No. I.4 (page 23) and FAQ No. D.8 (page 7), it is mentioned that the selected applicant has the option to change the Product Mix five times during the tenure of the PLI scheme subject to approval of the DOP at relevant point in time. In this regard, we understand that the selected applicants would option to change the Mix of the products (more than one product at a time) five times. While this is very clear, we would like to be doubly sure that our understanding is correct, accordingly, request you to kindly confirm our understanding.
	Yes. The interpretation is correct.