

## **Frequently Asked Questions- PLI Scheme for Pharmaceuticals**

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*Disclaimer: The FAQs and their replies have been made for ease of understanding of the Operational Guidelines of the scheme dated 1<sup>st</sup> June 2021, read with Corrigenda dated 30<sup>th</sup> June 2021 and 22<sup>nd</sup> 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 1<sup>st</sup> June 2021, read with Corrigenda dated 30<sup>th</sup> June 2021 and 22<sup>nd</sup> July 2021, will prevail over the FAQ.*

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

1. We understand from Appendix K that a single application has to be made by a company for multiple products falling in different categories. Kindly confirm.

Yes. Single application is to be made, whether it is for one or multiple products.
2. Clause 9.4 mentions that selected applicants shall submit sales data for the base year FY 19-20, domestic value addition plan etc. as required by PMA/ DoP. It would help to provide the format for the same- also why is domestic value addition plan required as the same is not a criterion at all in the Scheme.

It is clarified that domestic value addition is not a criterion in the scheme, however, information regarding the same may be collected.

All requisite formats will be shortly available on the scheme portal.
3. Is there a requirement to submit a projection/ project report with respect to future investments as part of the application process?

A brief technical plan on investments, proposed locations, project cost, means of finance, implementation plan etc. would be required to be submitted by all selected applicants.
4. Whether an applicant, who is MSME at the time of making an application, commit investment in P&M, more than INR 50 Crores and still be considered as MSME for the whole tenure of the said scheme? Will the applicant continue to receive incentives as MSME applicant even after surpassing the MSME limits as per MSMED Act?

Yes. As per clause 2.2.3, grouping of the applicant under MSME category is subject to applicant's registration as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India. Upon selection under the scheme, the MSME applicant will be eligible for incentive based on the yearly threshold criteria of minimum cumulative investment (Committed Investment in case of MSME) and minimum percentage growth in sales of eligible products as mentioned in Appendix B of the guidelines. As such, the scheme does not provide any restriction for MSME applying under the Scheme and can graduate to non-MSME entity based on its investments under the Scheme and other investments during the tenure of the scheme.
5. We are a newly formed company in FY 2020-2021 in the Category 2 API/ Intermediates. Most likely our commercial production is going to kick off in the current financial year 2021-2022. Since this PLI Scheme have the base year as FY 2019-2020 for computing GMR and incremental sales we will not have be having the same. We do not have any parent company with a similar business. Ours is a newly formed company. We will fall under Group C – MSME.

Are we eligible on the basis of proposed investment to apply in PLI Scheme? We will be incurring on Machinery, Equipment, product registration, R&D, Building, associated infrastructure etc. How the incentive in our case will be computed?

GMR is nil in your case, however, the Operational Guidelines does not specify a lower limit for GMR. Hence you will be eligible to apply for the Scheme under Group C. However, several selection criteria involve historical data of the applicant/ group companies, on which final ranking and selection would be done.

In case you are selected, all base year data will be taken as Nil, and incentive calculations will be made on the basis of that, subject to meeting other criteria of investment and sales achievement in the years between FY 2021-22 to FY 2027-28.

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

1. If there are two entities in the same group company (parent-subsidiary) where parent qualifies under Group A and subsidiary qualifies under Group B basis its products and standalone revenues and basis the total GMI and R&D expenditure of the parent & subsidiary taken together, subsidiary may qualify under Group A.

In such a scenario, can the subsidiary make an application under Group B and comply with the minimum cumulative investment and threshold net incremental sales for required for Group B?

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.

Only one applicant, on behalf of its group companies (as defined in Para No.2.13), shall be eligible for selection under 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 of the guidelines (read with corrigenda/addenda) and incentive criteria as defined in appendix B) pertaining to that group.

2. Whether sales of goods procured/ manufactured on a loan license/ contract manufacturing basis would be eligible for incentive under the Scheme. Whether trading revenue (P2P) & contract mfg. LLM (Loan License Manufacturing) to be included as part of global manufacturing revenue? P2P Revenue should be excluded while LLM revenue can be included.

For the purpose of threshold/incremental sales and incentives under the scheme, sales of pharmaceutical goods manufactured through loan licensing is allowed. However, sales of pharmaceutical goods manufactured through contract manufacturing (P2P) is not allowed.

For the purpose of GMR under the scheme, revenue of the applicant and its group companies from sale of pharmaceutical goods as booked in the books of accounts of the applicant and group companies and certified by the statutory auditor shall be considered. Revenue from sale of goods manufactured through contract manufacturing(P2P) or manufactured through Loan Licensing may be considered for this purpose.

3. In calculation of GMR for base year – Is export incentive included?

No, 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.

4. For calculating GMR - I goods are procured on a contract manufacturing basis, would the revenue from sales of such products would be counted towards GMR.

For the purpose of GMR under the scheme, revenue of the applicant and its group companies from sale of pharmaceutical goods as booked in the books of accounts of the applicant and group companies and certified by the statutory auditor shall be considered. Revenue from sale of goods manufactured through contract manufacturing(P2P) or manufactured through Loan Licensing may be considered for this purpose.

5. GMR - Consider a scenario, where the product manufacturing is completed at Factory A in the USA and such product is invoiced to Sales office in Singapore at ex-factory price and finally sold to a third-party customer from Singapore at sale price. For calculating GMR whether ex-factory price to be considered or the sale price to the end customer please clarify?

For the purpose of GMR under the scheme, revenue of the applicant and its group companies from sale of pharmaceutical goods as booked in the books of accounts of the applicant and group

companies and certified by the statutory auditor shall be considered. Revenue from sale of goods manufactured through contract manufacturing(P2P) or manufactured through Loan Licensing may be considered for this purpose.

6. This is regarding a query on the “Group Company” definition as per Pharma PLI Guidelines:  
The Applicant is a subsidiary of a Pharma Company incorporated in Singapore. There is a chain of about 20 companies in between the Ultimate Holding Company in USA and the Applicant.  
The query is whether all the entity's turnover will be required to be considered for the purpose of Global Manufacturing revenue (GMR). (i.e) Whether GMR includes revenue of Forward Chain (subsidiary companies) and Backward Chain (Holding Companies).  
Please note, that it may not be practically possible trace back the entire chain of entities.  
As per clause 2.3 of the operational guidelines, Group companies 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.  
For the purpose of calculation of GMR, only those group companies as defined above, who have booked revenue from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices in their books, shall be allowed. The same shall be certified by a Statutory Auditor.  
Manufacturing revenue from pharmaceutical goods and/ or IVD devices pertaining to applicant and all the group companies (as on the date of application) shall be considered for calculation of GMR. Gross manufacturing investment of applicant/ group company (as on the date of application) in India in 10 years during FY 2010-11 to FY 2019-20, shall be considered.
7. Clause 2.13 - Definition of the term 'group company' would cover a group company outside India as well. Confirmation needed.  
Yes, provided they satisfy the conditions for Group Company laid down in clause 2.13 of the Operational Guidelines.
8. 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 26% or more of voting rights in other enterprise; or appoint more than 50% of members of board of directors in other enterprise. There are PEs (e.g., Quadria, Chryscap) with stake more than 26% in multiple pharma companies.  
Will such pharma manufacturing company where any particular PE has invested be covered under the definition of Group Company for the purpose of GMR and counted accordingly?  
Is there any restriction that the Group Company should be based in India only – in other words, if there is a Group Company located outside India whether the same will be covered for the purpose of the Scheme A- Refer Clause 2.13 of the operational guidelines.  
As per clause 2.13 of the operational guidelines, Group companies 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, pharma company and PE which holds 26% or more stake in the subject pharma company are group companies. However, as per the query, multiple pharma companies where the PE holds 26% or more stake individually are not treated as group companies among themselves.  
Group Companies may be based both in or outside India.
9. Assume that a particular applicant chooses not to include turnover of a group company and prefers to remain in a different Group (say for example Group C as compared to Group B), would this be permitted under the Scheme - Refer Clause 2.2 of the operational guidelines

This is not permitted as per the Operational guidelines. Further, you may please note that the GMR of the Applicant and its Group Companies (as on date of application), 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.

10. If there are 2 companies, whose turnover and investment are combined for the purpose of GMR and GMI (classification under relevant Group A/B/C), and basis the consolidated numbers, happen to qualify as Group A, can they both take this consolidation as a base to file separate applications for different eligible products, as Group A applicants under the scheme? Essentially, the turnover considered for group classification would be overlapping in this case.

No. Only one applicant from the group (Group Companies as defined in Operational Guidelines) can apply under the scheme.

### C. Eligibility for Application related FAQs

1. Contract Development and Manufacturing Organizations (CDMOs) – Applicant manufactures certain products as CDMO, can such products be included in the application for PLI. Are such products eligible for incentives?

In case the Applicant is the CDMO and manufacturing eligible products under the arrangement, and the sales is booked in the P&L account of the Applicant and its Group Companies, as certified by Statutory Auditor, then the sales shall be considered for the purpose of incentives.
2. In case of Green Field project for exports, gestation period would be 2 to 4 years. The scheme currently does not address this. For green field project, companies will not have any base year data. How, will this be addressed for computing incentive?

In respect of an applicant where the sales of eligible products for FY 2019-20 is nil, for the purpose of calculating incentive, the base year sales would be taken as zero. However, the Applicant and its Group Companies are required to achieve the threshold/ incremental sales for the subsequent years, as given in Appendix- B of the Operational Guidelines.
3. How is the PLI scheme is going to accommodate the green field investments in new company formed under section 115BAB. Can the new company (subsidiary) formed for green field projects u/s 115BAB be a co-applicant with the parent and claim the investment and production for PLI along with parent?

Co-applicants are not allowed under this PLI Scheme. Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.

Base line data for FY 2019-20 of green field applicant will be taken as Nil and calculations of incentives will be based on that.
4. Is it mandatory to manufacture and market the products only in India or can a selected applicant export the eligible goods as well?

The approved eligible products have to be manufactured in India only. The scheme does not mention any specific market.

#### D. Eligible Products related FAQs

1. Since product categories are very broad, would products like generics (and not complex generics) be regarded as covered under the categories or a specific approval from DoP would need to be taken?  
As per Appendix A, many generic drugs are covered under Category 3 of the scheme. In case of any doubt as to whether any particular drug is covered under this scheme or not, the same may be referred to PMA beforehand.
2. If a product is not falling under any of the given categories and approval from Technical Committee has to be taken, would such approval be granted prior to filing the application or post-filing?  
If the product is not falling under any of the given categories as per Appendix- A of the Operational Guidelines, the same shall not be considered.
3. Some Products may fall under different categories, how do we classify them in the application form?  
Categorization of the products should be done by the applicant 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. 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.
4. Can eligible products falling under the 3 categories be considered together for being part of the 'product mix' under the Scheme? Further, can such eligible products be manufactured in different locations/ facilities of the applicant, including loan licensee premises?  
Yes. Applicant may apply for more than one Eligible Product, belonging to any of the 3 categories, under the scheme. Further, the eligible product may be manufactured in different locations/ facilities of the Applicant and its Group Companies in India, including loan licensee premises.
5. Whether Eligible products should be seen at sub-category level OR per molecule level OR at category/overall level  
Categorization of the eligible products will be seen as per Appendix A of the Operational Guidelines.
6. Incentive to be calculated based on incremental sales of eligible products approved for the applicant. Change in product mix permitted max. five times during scheme period (until mar 28)  
How to take care of new product launches under existing sub-category or incorrect classification of sub-category [e.g. complex generic product]?  
All products with expected incremental sales under given sub-category to be included in the application list. Since scheme is for six yrs; such list should be revised typically yearly once at the time of budget.  
Yes. As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, a clarification is needed on eligibility/ categorization of specific products, a list may be sent to the PMA, so that the same can be referred to the TC.
7. Definition for some of the sub-categories like Complex generics, orphan drugs, complex excipients etc. is not existing. What if in absence of the definition, product is categorized under Category 1 - Complex generic (10% incentive) and government rejects the same – No provision to reclassify under Category 3 – say anti diabetic?  
The product should be categorized under the correct category as per Guidelines. In case there is confusion on categorization of a specific product, the same may be referred to the PMA beforehand.

8. What about product mix changes - Policy gives limited number of changes to be allowed. Market dynamics may force to reconsider product mix in the investment site.  
The policy has considered the same and has allowed change of products to the extent of five times vide clause 7.2.2 of the Operational Guidelines.
9. Appendix A provides category 1, category 2 and category 3 of eligible products. However, scheme does not define what would be covered under each of the line items mentioned therein (eg what is covered under complex generic drugs and what would not be considered as complex generic drugs).  
Whether the word "Drug" as referred in the Category 1 and 3 of goods includes API or covers only formulations?  
Guidelines would be required to have consistency of what gets covered under Category 1 products and not under Category 3 and vice versa. What is the key differentiator / criteria of Category 1 and Category 3 products eg other drugs as approved are covered in both the said categories? This is relevant as the incentive rates changes significantly under both categories.  
As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, you need clarification on eligibility/ categorization of specific products, you may send us a list, so that the same can be referred to the TC.  
Only Category 2 is for APIs, Category 1 and 3 covers the drug product/ formulations. 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).  
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.
10. New products manufactured in the 2nd or 3rd year of the tenure of the scheme: In case company applies for the Scheme for products which it starts manufacturing from FY 2023-24/2024-25, there will be no revenue for those products in FY 2022-23. Can such products be eligible under the Scheme?  
Yes, it can be eligible.  
However, year in which (say FY 2022-23) the sale of the said eligible product is nil, incremental sale of that product will be considered as zero and no incentives will be given for that particular year.



## E. Selection Parameters and Ranking related FAQs

1. **Would capital investment in R&D get included under the two qualifying criteria viz. GMI (with 30% weightage) and R&D expenditure (with 40% weightage)?**  
In selection criteria-1 (for Group A/B applicants) the Gross manufacturing investment in India, includes capital investments for R&D facilities.  
In selection criteria-3 (for Group A/B applicants) R&D expenditure (in India or abroad) will include both capital and revenue expenditure.
2. **Clause 4.1 – One of the selection criteria is Gross manufacturing investment for the past 10 years. Whether such gross manufacturing investment would be considered on an average basis or would be seen in totality? Case in Point: Companies/ groups which are relatively new, i.e., which have been set up in FY 2017 or thereafter, would have made comparatively lesser investment.**  
The selection of Applicants will be based on Gross Manufacturing Investment (GMI) of Applicant/ Group Company in India for 10 years as given in Para No. 4 of the Operational Guidelines.  
Accordingly, the GMI will be the total value.
3. **Would such applicants rank lower vis-a-vis an applicant which has presence for the past 10 years, and therefore greater total investment amounts.**  
All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria given in Appendix J of the Operational Guidelines. The applicant securing highest marks shall be ranked 1 followed by Applicant securing second highest marks. The selection of the Applicants shall be in order of their ranks vide clause 4 of the Operational Guidelines (read with Corrigenda/Addenda).
4. **For the purpose of determining past manufacturing investment and R&D expenditure, would expense booked in financial statements be regarded as eligible?  
Would such expense incurred outside India by applicant/ group company be considered?**  
As per clause 2.22 of the Operational Guidelines, gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities will be considered for arriving at Gross manufacturing Investment.  
Accordingly, such investments as defined above which are capitalized in the books of accounts and certified by the Statutory Auditor will be considered for the purpose.  
Investment made outside India shall not be a part of GMI as used in selection criteria-1 for Group A/B/C (Non-MSME) Applicant.  
However, R&D expenditure made outside India shall be considered while computing R&D expenditure used as selection criteria-3 for Group A and B applicant.
5. **Gross Manufacturing Investment (GMI) is an important criterion for selection – The same has been defined in clause 2.22. This will include gross capital investment in manufacturing facilities including capital investments for R&D facilities. Guidelines should be provided to ensure that there is consistency in disclosure of the same for application purposes– for e.g. say in FY 19-20 there could be CWIP (whether the same should be included in GMI), also say an applicant has in the period from 10-11 to 19-20 acquired an entity for a consideration which includes certain intangibles such as IP, product patents, goodwill etc. Will the same be considered as "Gross manufacturing investment" for selection? What should be factored in GMI in case of acquisition of other entity?**  
As the term suggests, GMI would include capital investments in Manufacturing facilities.

Typically, CWIP in the FY 2019-20 may not be considered under GMI, as the same does not guarantee conversion to manufacturing assets until the completion of the project.

Intangibles shall not be allowed.

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 clause 2.22) at the time of acquisition as certified by the statutory auditor/ ICA shall be included for the purpose of calculation of GMI.

6. In respect of the 3 parameters of selection criteria – criteria 1 depends on GMI which would include the capex incurred for R&D. Criteria 3 refers to R&D expenditure which would include Capex incurred on R&D. Accordingly, is it the intent to allow factoring the quantum of R&D expenses in both criteria 1 and 3 (for years 17-18 to 19-20) from eligibility weightage perspective? Would request clarification on the same- Reference to Clause 4.1 on selection of applicants

In Selection criteria-3 (for Group A/B applicants) R&D expenditure (in India or abroad) will include both capital and revenue expenditure.

Only expenditure incurred during the year would be allowed for R&D expenditure. Non-cash expenses, such as depreciation, etc., will not be allowed.

7. Selection Parameter Sr. No.1: 3, R&D expenditure is this includes only R&D expenses (Accounted in P&L) or also R&D spend in capital in nature?

Both capital and revenue expenditure under R&D shall be considered.

## F. Selection Procedure related FAQs

1. Clause 4.6 refers to Foreign MNCs, which is not defined - would help to clarify the same as the same would be relevant from selection standpoint. Also, Appendix I which is checklist for preliminary assessment of application by PMA does not have any reference to category of Foreign MNC  
An Applicant registered in India and having more than 50% shareholding by foreign company(ies) (as defined in Companies Act, 2013) may be considered as a foreign MNC for the purpose of consideration under the Scheme.
2. Clarity on timelines for DoP approval of applicants shortlisted by PMA.  
As per clause 9.2, timeline for selection is 90 days from the date of closure of application window.

### G. Eligible Investment related FAQs

1. What if part assets are purchased initially and then later after two years these were sold by the company (reason could be new technology, new equipment with better capacity is available)  
Gross Investment value of the said sold assets would be deducted from the Cumulative Investment for that year in which sale is made.
2. If there are assets created at CMO plant, will they be considered under the scheme as investment?  
The assets created by Applicant and its Group Companies should be capitalized in the books of accounts of the Applicant and its Group Companies as certified by the Statutory Auditor or Independent Chartered Accountant, whichever is applicable, except the eligible investments with respect to 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. It may be noted that sales of products got through Contract Manufacturing will not be permitted for calculation of incentives as per the Operational Guidelines.
3. Whether investment to be seen based on cash outflow or based on capex invoice dt or based on actual capitalization? [Investment should be seen as per invoice dt of capex incurred.]  
Both invoice date and capitalization should be within the investment period (FY 2021- FY 2026) under the scheme. For any particular year, the investment will be considered under eligible investment based on the capitalization of the asset in the books of accounts for that year.
4. If a product is likely to commercialize in FY 27-28, but R&D and capex are incurred before, can the investment still be considered?  
In case the eligible product, which is likely to commercialize in FY 2027-28, is committed during the time of Application, eligible investment made towards P&M or R&D (as defined in clause 2.15 of the Operational Guidelines) in respect of the committed product, from 01.04.2020, can be considered under the scheme.  
If the same product is committed by the Applicant at the time of later change (as permitted by clause 7.2.2 of the Operational Guidelines), eligible investment made towards P&M or R&D (as defined in clause 2.15 of the Operational Guidelines) in respect of the committed product, from 01.04.2020, can be considered under the scheme.
5. If the expense incurred on exhibit batches would be regarded as eligible expenditure?  
In case expenditure of exhibit batches 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 and certified by the statutory auditor, the same shall be considered under eligible investment.
6. Will purchase of samples be considered in R&D expenses.  
In case purchase of samples 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 and certified by the statutory auditor, the same shall be considered under eligible investment.
7. A company which has applied under the earlier PLI Scheme for API/KSM in 2020 but was not selected for whatever reasons. However, one of such APIs does flow into the formulation and gets covered under the eligible Product list under the new PLI Scheme of June 2021.

In this case, whether the investment made in the API site to create such API capacity can be considered for calculating the Rs. 200 Crs per year investment from the Base Year (after 1-04-2020) as defined in this PLI Scheme of June 2021?

Yes, if the API produced from the investment is being used only in the manufacturing of the drug formulation (which is an eligible product under current PLI Scheme) by the applicant. The investment made in such site on or after 01-04-2020 may be considered as eligible investment subject to the same being certified by the statutory auditor of the Applicant.

8. Para 2.15.3 of the guidelines provides for expenditure incurred on Transfer of Technology agreement.

In connection to the same, whether expenditure incurred on 'in-licensing milestones payments' will be considered as part of Transfer of Technology agreement or not being "Eligible Investment".

To be considered under the eligible investment, the "in-licensing milestones payments" expenditures should be made towards the cost of technology and initial technology purchase in relation to the eligible product. The same should be clearly defined in the formal legal document in respect of the licensing agreement between the parties. The expenditure is also to be capitalized in the books of accounts of the applicant.

9. Whether investment needs to be made in own factory or can be made even in Job worker location since intermediates would be manufactured by job worker on behalf of principal manufacturer and in-turn would be used by the principal manufacturer

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 its Group Companies and compliance to the conditions laid down in clause 2.15 and clause 6 of the operational guidelines (read with the Corrigenda/Addenda).

10. We understand that investment criteria include investments made on or after April 1, 2020 & linked to product category. We need clarity on:

a. Whether incentives are linked to product from new investment only or includes incremental sales even from prior investments.

b. Whether investment will be at a group company level or individual entity level.

a. The incentives are linked to incremental sales even from prior investments subject to compliance to the conditions pertaining to investment as per clause 2.1.5 & Appendix-B (year-wise minimum cumulative investment by per Participant is given).

b. As per the definition given in Clause 2.1, an Applicant for the purpose of the Scheme shall be any Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP) or a Company registered in India. Investment of the Applicant and its Group Companies, in relation to the Eligible Products under the Scheme, shall be considered.

11. In case of application for multiple products, whether the investment and sales criteria to be met for each product or for all products put together?

Applicant presently has multiple manufacturing facilities across India and the products to be included in PLI application will be manufactured in all such manufacturing facilities. Applicant makes capital investments for improvements or enhancement of production capacities of all the manufacturing plants which includes facilities for manufacturing products under application. Can such investments made at entity level be considered as eligible investments under the PLI scheme?

Investment and sales criteria are to be met on an aggregate basis for all approved eligible products.

Investment made in the manufacturing plants that belong to the Applicant and the group company(ies) and also conform to the Eligible Investment criteria as laid out in Clause 2.15 of the Operational Guidelines will be eligible. Please also be guided by Clause 6.2.3 of the operational guidelines.

12. Should the eligible investment be restricted to a green field project?  
There is no specific requirement that the investment to be made for eligible products should be only in a green field facility. The same could be for expansion of current facilities as well. Further, it was specifically clarified that the Plant, Machinery and Equipment of the Project approved under the Scheme can be used for manufacturing of other pharmaceutical goods as well, subject to a declaration by the applicant.  
The interpretation is correct. For threshold/ incremental sales, both sales of eligible products from existing or new facility may be considered.
13. Should there be a clear nexus between the investment and the incremental sale of eligible products?  
While the guidelines state eligible investment means expenses incurred in relation to the eligible products, there is no specific requirement of nexus between the investments with the eligible products. For example, as regard the expenditure incurred on Transfer of Technology (ToT) agreements, the same is defined to include only the expenditure on cost of technology and initial technology purchase in relation to the eligible product.  
However, for new Plant, Machinery, Equipment and Associated Utilities, no such requirement is specifically provided in the guidelines. Further, it was specifically provided that the Plant, Machinery and Equipment of the Project approved under the Scheme can be used for manufacturing of other pharmaceutical goods.  
Having said that, the guidelines state that the Plant, Machinery, Equipment and Associated Utilities shall be used in regular course for manufacturing of goods under the eligible product categories. Accordingly, although there is no requirement of direct nexus between the investment and the manufacture of eligible products, a declaration has to be filed each year about the usage of the machinery.  
The relation between Investment and Incremental Sale of the Eligible Product would be in terms of the Operational Guidelines.
14. Whether Investment of Rs. 1000 crore on a cumulative basis (minimum 200 crore per year) over a 5-year period up to FY 2025-26 is required to be made only by the applicant company on a standalone basis or such investment can be made by more than one Indian group companies (e.g., Indian parent and its wholly owned Indian subsidiary) will be considered as an eligible investment?  
The eligible investment made by the Applicant and its Group Companies shall be considered.
15. Clause 2.15 - If any capital investment is funded by an International Agency, will it qualify as eligible investment?  
Yes, there is no restriction for funding by an International Agency. However, grant from Govt. of India or any State/ UT Government will have to be shown separately and will not be considered towards eligible investment under the scheme.
16. Will leased assets be considered as part of investment or not?  
Investment should be capitalised in the book of accounts of the Applicant and its Group Companies, and is subject to satisfaction of all clauses of clause 2.15 and clause 6 of the Operational Guidelines.
17. Dossier fees, consultants' fees? will this also be considered in the expenses? What about current WIP projects?

No. Expenditure mentioned under clause 2.15 would only be considered.

WIP will not be considered for Investment. Only the investment (except R&D and Product Registration expenditure as per clause 6.1.5) which are capitalized in the books during the investment period would be considered.

18. Are IT assets covered under investments? In a manufacturing plant there is substantial investment in IT and is a significant part of QA/ QC/ Manufacturing– it is suggested that this should be included. In current regulated environment industry invests a great deal in IT.

Expenditure on IT systems as a part of QA/ QC/ Manufacturing is incorporated in the operational guidelines vide Corrigendum/ Addendum dated 30.06.2021. The same is available on the website of the DoP/ PMA.

19. Whether investment will be considered on proportionate basis in case the investment in plant and machinery is done for both eligible as well as non-eligible products

As per the Operational Guidelines, eligible investment in relation to the eligible products only will be considered. 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. However, 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.

20. In a certain project if there are some grants received for funding small part of the project, will the rest of the expenditure (net of grant) still be considered as investment under this scheme or total value.

Yes, the rest of eligible investment as per the Operational Guidelines, net of any Government grant received, will be considered under the Scheme, provided it satisfies all criteria mentioned in clause 2.15 and 6 of the Operational Guidelines.

21. Investments made from 01.04.2020 in respect of eligible products would be considered under the Scheme. Thus, if an investment of Rs 300 Cr has been made from 01.04.2020 till date, would the same would be considered for the minimum committed investment for FY 21-22?

Yes, eligible investment done from 01.04.2020 to 31.03.2022 will be considered under Minimum Cumulative Investment for the FY 2021-22.

22. Investment threshold is Rs. 200 Crores per year. However, in case any company, makes investment of Rs.250 Crores in Year 1 and an investment of Rs.150 Crores in the Year 2; whether the surplus investment of Rs. 50 Crores in Year 1 would be considered for calculating the total investment of Year 2?

Eligible investment as per Para No. 2.15 of the Operational Guidelines can be done as per business requirement of the Applicant, either in one go or in tranches during the Scheme Investment period. However, year wise minimum cumulative investment criteria and incremental net sales criteria both have to be met by the Applicant as per Appendix B of the Operational guidelines.

23. Whether Capital Work in Progress (CWIP) would be covered? [CWIP should be included [consistent with future investment criteria]

No. Investment should be capitalized in the books of account of the Applicant and its Group Companies during the investment period.

24. Whether land to be included? Whether Investment in intangibles (ie brand acquisition cost) to be included in investment? [As there is no specific exclusion, land/ Intangibles can be included.]

Investment on land is not covered vide clause 2.15.5 of the Operational Guidelines.  
Intangibles like brand acquisition cost are also not covered as an eligible Investment head as per clause 2.15 of the operational guidelines.

25. Are R&D equipment excluded from the purview of 'eligible investment'?  
It is eligible, provided it is not second-hand.
26. Whether R&D expenditure incurred outside India be considered as eligible investment?  
No, R&D expenditure incurred in India only will be considered as Eligible Investment for the purpose of incentive eligibility.  
May also refer to clause 2.15.4 for eligible expenditure outside India.
27. Whether expenditure on salary of staff employed in the R&D unit would be considered as eligible investment?  
R&D Expenditure as mentioned in clause 4.1 and 6.1.5 of the Operational Guidelines, 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.
28. Will litigation expenses (challenging the patent) eligible for Investment?  
No, litigation expenses are not covered under the eligible investment for the Scheme.
29. We request for clarity on all the components of R&D, etc. which will be allowed and not allowed to be considered for investment as one company may leave out some components due to lack of clarity in the guidelines which other companies are considering in their application and hence lose their competitive advantage.  
R&D expenditure, which has been 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 and certified by the statutory auditor, shall be considered under eligible investment.  
May also refer to clause 2.15.4 for eligible expenditure outside India.
30. If an investment of 100 Cr has been made in a new plant and only 3 out of 5 products manufactured in the plant are considered for the PLI Scheme, can the full 100 Cr of investment be considered for the minimum capital contribution?  
As per clause 6.2.3. of the Operational Guidelines, the Plant, Machinery and Equipment in relation to the eligible products 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.
31. Whether a company which has applied under the earlier PLI Scheme for API/KSM in 2020 but not selected then, can now apply under this 2021 PLI Scheme for a product covered in the list under earlier PLI for Bulk Drug/KSM scheme? If yes, whether the Investment made then (after 1.4.2020) can be considered as eligible Investment?  
As per Appendix A of the Operational Guidelines, under category-2, API/ KSM/ DI are eligible except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs) in India" notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/16/2020-Policy, dated 21/07/2020 in Part-I, Section 1 of the Gazette of India (Extraordinary).



32. Clause 6.2.3 of the Operational guidelines provides that 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 pharma 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 – In this context, following clarifications are sought a) in this scheme, Project is not approved but eligible products of the applicant would be approved – need to correct the same, b) format of aforesaid declaration is not provided in the operational guidelines
- a) In clause 6.2.3, the word project refers to the eligible products under the scheme.
- b) Respective format for the same would be made available to the applicants selected under the scheme as per the operational guidelines.

33. Clause 6.1.1. mentions that Investment made on or after April 1, 2020 is counted for the purpose of the Scheme. Appendix B mentions that the minimum cumulative investment per participant for first year (i.e. FY 2021-22) should be either Rs. 200/ 50/ 10 crore depending upon the Groups. Further, clause 7.1.1 states that the selected participants in the scheme will be eligible for incentives on incremental sales of eligible products based on yearly threshold criteria including minimum cumulative investment.

Need clarification as to whether the minimum cumulative investment of FY 2021-22 should also include the investments, if any, made by the participant in 2020-21. This would help avoid confusion for the Trade. The eligibility criteria from the perspective of investment is minimum cumulative investment and not equivalent investment every year during the tenure. Therefore, the investment made on or after 1 April 2020 shall be considered for the investments to be made during FY 2021-22 or thereafter based on the amount invested. This logic should apply to all the subsequent years i.e. investment made in excess of minimum cumulative threshold for a year should be considered towards fulfilment of criteria for the next year. Should the eligible investment be restricted to a green field project? From the guidelines it does not appear to restrict to green field only, however confirmation on the same would help to have clarity for the applicants.

Should there be a clear nexus between the investment and the incremental sale of eligible products? Whether goods manufactured from new investment only will be considered towards sale of eligible products / incentives thereof under the Scheme. The scheme is in relation to the eligible product and there is no specific restriction to make an investment only in greenfield project. The eligible products being manufactured at any of the existing sites of the applicant can be considered subject to meeting other criteria. Further, SI. No. 6 of the Quarterly Review Report requests for manufacturing locations of the selected applicant and not any approved manufacturing locations (there is no concept of approved manufacturing locations under the Scheme). Therefore, it appears that if the applicant can substantiate incremental sales of the eligible products from any of the manufacturing sites, the incentives shall be granted. Would require confirmation to this understanding.

Investment done from 01.04.2020 to 31.03.2022 would be counted under cumulative investment for FY 2021-22.

Applicant may choose to invest as per business requirements. Actual cumulative investment done by the applicant must meet the minimum cumulative investment criteria as defined in Appendix B of Operational guidelines, for being eligible for incentives

Investment may be made in the existing plant or a new location, as per choice of the Applicant. However, Applicant has to provide information about all the locations where investment has been made in QRRs/ as otherwise instructed. Sl. No. 6 of the Quarterly Review Report for manufacturing locations of the selected applicant may be read as manufacturing locations of all approved eligible products of the Applicant.

Sales of the eligible products would be considered from existing or new setups for the purpose of calculation of incentives.

34. Clause 6.1.4 clarifies that the date of purchase invoice would be considered as the date of investment under the Scheme. Clause 6.1.5 provides that the heads of investment, based on which eligibility is being determined, should be capitalised in the books of accounts of the applicant as certified. Need confirmation that there is no requirement that the heads of investment should be capitalised in the same year of purchase invoice – even if the same is capitalised in subsequent years falling outside the Scheme period, the same will be considered as part of eligible investment per se.

As per the scheme guidelines, to be considered as eligible investment, both invoice date and capitalization should be within the investment period under the scheme.

With regard to minimum cumulative investment for a particular year, eligibility of investment will be based on the capitalization of the investment in the books of accounts in that year.

Further, as per clause 6.1.5, expenditure on R&D, product registration may be in the nature of capital/ revenue expenditure where such is certified by the Statutory Auditor/ ICA. Therefore, expenditure in respect to R&D and product registration may also be included under the eligible investment in the year of expenditure.

35. Clause 6.2.1 and Clause 6.2.4 inadvertently refers to clause 2.16.1 as compared to clause 2.15.1– this may be corrected

Corrigendum/ Addendum dated 30.06.2021 has been issued by DoP regarding the same. The same is available on the website of the DoP/ SIDBI.

36. Concept of Successor-in-interest has been defined in clause 2.20. The same shall mean the new or re-organised entity formed after the merger, de-merger, acquisition, transfer of business or significant change in ownership of an applicant. Clause 12.1 provides that in case of change of shareholding pattern leading to a successor in interest then the same should be informed to PMA who would then inform DoP for approval from incentives perspective. Clause 12.3 provides that in case of a successor in interest, all investment undertaken by the applicant to whom the approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the DoP, as may be deemed appropriate.

Clarification is required as to whether in case of acquisition done in say 2020-21 or thereafter by an applicant for business having eligible products, the base sales turnover of 19-20 (period prior to acquisition) would be counted for computation of incremental sales as per clause 7.2.5. The said clause does not provide any restriction. Also whether acquisition made during the period of scheme would qualify for investment (given that it would value towards plant, machinery etc.)

The base year sales of FY 2019-20 of the acquired business would be taken as part of the base year sales of the Applicant.

As per clause 6.1.2 of the Operational guidelines, no second-hand machinery is allowed under the Scheme. The assets acquired as part of the acquisition would be used assets and therefore, are inadmissible as per the above Para.

37. As per para 6.1.2 of the guidelines, investment in second hand R&D equipment is ineligible. However, we understand that investment in new R&D equipment is eligible and covered under 2.15.1 and 2.15.2. Request you to please confirm the same.  
The interpretation is correct.
38. Whether a company which has applied under the earlier PLI Scheme for API/KSM in 2020 but not selected then, can now apply under this 2021 PLI Scheme for a product covered in the list under earlier PLI for Bulk Drug/KSM scheme? If yes, whether the Investment made then (after 1.4.2020) can be considered as eligible Investment?  
No, as the 41 items (APIs/ KSMs/ Dis) in the Bulk Drug PLI scheme have been excluded from the list of eligible products for this PLI Scheme.  
Please refer to Appendix A of the Operational Guidelines.
39. Whether Investment of Rs. 1000 crore on a cumulative basis (minimum 200 crore per year) over a 5 year period up to FY 2025-26 is required to be made only by the applicant company on a standalone basis or such investment can be made by more than one Indian group companies (e.g. Indian parent and it's wholly owned Indian subsidiary) will be considered as an eligible investment?  
Investment in India, made by the Applicant and its Group Companies as per the eligibility given in clause 2.15 of the Operational Guidelines shall be considered while calculating incentives.
40. As Eligible investment: is made on or after April 01, 2020. In case of R&D Expenditure cases are there spend is spread over more than year for new products. In case of our existing products under development and selected under scheme whether R&D spend done before April 01,2020 eligible as Investment.  
No. Only expenditure on R&D done after April 01, 2020 will be allowed for calculation of Eligible Investment under the Scheme.
41. The guidelines provide that all the non-creditable taxes and duties to be included in the expenditure for calculating the investment. Are the benefits derived from RODTEP scheme and PLI scheme mutually exclusive or both can be claimed simultaneously for the same products?  
As per Clause 7.1.6 of the Operational Guidelines, eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa.

#### H. Threshold/ Incremental Sales related FAQs

1. **Whether P2P based product sales (Traded goods) in India to be included?**  
As per the Operational Guidelines, P2P based product sales and any other trading revenue, will not be considered for threshold/ incremental sales at the time of calculation of incentive.
2. **If an applicant meets the investment criteria only from R&D and uses CMO(s) for manufacturing, where the manufactured products are sold through the applicant, will such entity be eligible to apply for the scheme.**  
Cumulative Investments under the scheme may be made only from eligible R&D expenditure as per clause. 2.15.2.  
Revenue from sale of eligible products produced under contract manufacturing shall not be considered for calculating threshold/ incremental sales. However, revenue from sale of eligible products produced under loan licensing manufacturing by applicant will be considered for calculating threshold/ incremental sales.
3. **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 of the Applicant 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 clause 2.16 of the Operational Guidelines.
4. **Since a cumulative investment number would be given to the authorities, along with the list of products proposed to be manufactured, what would happen if the products' sales committed at the time of making the application is not achieved?**  
Or in case out of 10 products committed at the time of making the application, only 8 are actually manufactured and sold. API prices generally fall - if there is 10 % growth in volume but 20 % degrowth in value. How to handle such situation which is common in API.  
No incentives would be given for the year in which sales are not achieved as per Appendix B of Operational Guidelines.  
Further, for incentive calculation, the aggregate sales of all the eligible products would be considered. However, data will be submitted by Applicants for sales of individual eligible products at the time of claim.
5. **Clause 7.1.3 read with Appendix B– Whether average growth in sales would be required to be met for each product separately or for all the products applied for, taken together? For e.g. if for one product, a 9% growth is achieved and for the other product it is only 6%, the average growth for both products taken together is 7%. Would this suffice?**  
The aggregate sales, during the year to which the claim pertains, of all the eligible products would be taken for incentive calculation. However, data will be submitted by Applicants for sales of individual eligible products at the time of claim.
6. **Whether incremental manufacturing sales of related parties, where investment is made by the applicant, will be considered?**  
Investments made in compliance to clause 2.15 and 6, in the books of accounts of the applicant and its group companies, shall be considered under eligible investment.

Incremental sales of all approved eligible product in respect of the applicant will be considered for incentive. Any sales from related party will not be considered for arriving at incremental sales.

7. In case in any of the year, the applicant company achieves 12% sales growth over previous year which is 5% above the threshold growth of 7% and in the next subsequent year, growth rate achieved is 5%. Every year has a new threshold sales criterion as given in the Appendix B of the operational guidelines. In case, any applicant does not meet the criteria of threshold sales, the applicant will not be eligible for any incentive for that particular year.
8. In case the applicant cumulative CAGR is equal or higher than 7% (as compared to first year), though in one of the years, the growth is lower than 7%. Under this situation, the applicant company would be eligible for incentive in the year in which sales growth registered was 5% but CAGR equal or greater than 7% as compared to the first year?  
No, CAGR is not a criterion for calculation of incentive.
9. What if the growth in a particular year is less than 7% (reason could be - pandemic, Price erosion etc)  
As per the operational guidelines, if the Threshold/ Incremental sales as per Appendix B is not achieved by an Applicant in any given FY, that applicant will not be eligible for any incentive for that particular year.
10. For the purpose of determining eligibility of incentive for first year i.e. FY 22-23, the threshold sales in FY 22-23 for eligible products has to be greater than Rs. 50 Crore in case of a Group A participants. Does this Rs 50 Cr refer to incremental sales as compared to sales in the base year of FY19-20? Whether the sales in FY 23 have to be computed in aggregate level to arrive at this minimum Rs.50 Crs threshold or it should be computed product wise?  
The threshold sales of Rs. 50 cr. for FY 2022-23 does not mean incremental sales.  
For subsequent financial years, i.e. FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the previous FY for the approved eligible products.  
Aggregate sales of all approved eligible products must be Rs. 50 Crore for Group A applicant for FY 2022-23.
11. For determination of Incentive eligibility whether threshold Sales of Rs. 50 crore for Eligible Products in FY 2022-23 is the aggregate sale of all the approved eligible products or the threshold to be achieved is for each of the approved & eligible product (i.e. Rs. 50 crore x No. of Products)?  
Aggregate sales of all approved eligible products must be Rs. 50 Crore for Group A applicant for FY 2022-23.
12. Base year of sales considered is 2019-20 and the first year wherein we would measure incremental sales is 2022-23; Whether DoP would measure the incremental sales directly comparing the sales of eligible products between 2019-20 and 2022-23 to verify whether the applicant met the criteria for incentive in the Year 1?  
Aggregate sales of all approved eligible products must be Rs. 50 Crore (Group A)/ Rs. 10 crore (Group B)/ Rs. 1 crore (Group C)/ Rs. 50 lakh (Group C MSME) applicant for FY 2022-23.  
Further, incentive calculation will be done in the following way, subject to achievement of Minimum Cumulative Investment and Threshold Sales (described above):  
Incentive= (Sales of approved eligible products for FY 2022-23 minus Sales of those products in FY 2019-20) \* Incentive Rate for the Product Category.

13. All New products would be having Nil revenue in 19-20 & hence would they be eligible for incentive on 100% of revenue if such products are falling in the given sub-categories. [New products being part of given sub-categories should be eligible on full sales value for the incentive.] If all the products are new products having sales from FY 21-22 onwards, will the incentive computation start as zero base year (FY 19-20) sales?  
Yes. Base year sales i.e., for sales for FY 2019-20 in respect of the eligible products will be considered as zero in the instant case.
14. In case of acquired brands due to M&A; should the base sales be taken as NIL? [For M&A cases also, the acquired brands should be considered as new brand for the applicants.]  
Base values of acquired brands will be taken into account for arriving at incremental sales.
15. What if there is a situation like Pandemic - resulting in less turnover and thus failure to achieve YOY growth.  
These are very specific situations which may not happen frequently in the regular course of business. The Scheme will be implemented as per the Scheme guidelines.
16. If we are asked to make huge quantity of a drug where sales value is low or asked to do job work for other company. E.g. recently companies were forced to manufacture Remdesivir - how to handle?  
This is a very specific situation which may not happen frequently in the regular course of business. The Scheme will be implemented as per the Scheme guidelines.
17. Clause 7.2.5 refers to baseline sales of the eligible product in 19-20. If there was no sales of eligible product in 19-20, can the same be factored as NIL for the purpose of computing incremental sales during a given financial year of the scheme.  
Yes. In case there was no sales of eligible product in FY 2019-20, the base year sale will be considered as NIL.
18. For calculating the incremental sales as compared to the Base Year 2019-20, please confirm as to whether incremental sales of both Formulation and APIs of the eligible Products can be considered under the PLI Scheme of June 2021 or only incremental sales of Formulation would be considered?  
Both can be considered if the products are eligible under the scheme and approved by the DoP.
19. Appendix B provides that for the purpose of determining eligibility of incentive for 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than a specified amount depending upon the group of the applicant. Need clarify on whether the increase by Rs 50 crores is to be factored by comparing with base turnover of said eligible products in FY 19-20 or should the same be considered by comparing with sales of eligible products done in FY 21-22 (a year prior to FY 2022-23)  
As per, Appendix B of the guidelines, 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 has to be greater than specified amount depending upon selected applicant's group. For example, for group A applicant the threshold sales of the first year i.e. for FY 2022-23 is Rs. 50 Crore.  
Further, incentive under the scheme shall be calculated on the incremental sales of the Eligible Product(s) approved to the participant, subject to meeting the criteria of threshold sales and minimum cumulative investment for the corresponding year, as given in the Appendix B of the guidelines.  
Incremental sales mean sales of approved eligible products during a given Financial Year minus the baseline sales (FY 2019-20) of the eligible products.  
For example, if sales from approved eligible products for the year 2022-23 is Rs. 60 Crore and the baseline sales of approved eligible product (FY 2019-20) is Rs. 20 crore, the incremental sales shall be Rs. 40 Crore.

20. Base year of sales considered is 2019-20 and the first year wherein we would measure incremental sales is 2022-23; hence, whether they would measure the incremental sales directly comparing the sales of eligible products between 2019-20 and 2022-23 to verify whether the applicant met the criteria for incentive in the Year 1?

Criteria for getting incentive in FY 2022-23 is:

Threshold sales in FY 2022-23 for all eligible products, taken together, to be greater than Rs. 50 crore in case of a Group A participant, greater than Rs.10 crore in case of a Group B participant, greater than Rs.1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant.

Calculation of incentive would be based on Net Incremental Sales i.e: Actual net sales of eligible products in FY 2022-23 minus the net sales of eligible products in base year i.e. FY 2019-20.

21. For working out the amount of Incentive to an Applicant whether the sales of eligible products of Group companies of Applicant (e.g. Indian Parent and it's wholly owned subsidiary) is to be considered or sales of only Applicant company on a standalone basis is to be considered?

Sales of eligible products by the Applicant and its Group Companies as per the eligibility given in clause 2.15 of the Operational Guidelines shall be considered while calculating incentives.

## I. Claim for Incentive related FAQs

1. Clause 12.4 of the Guidelines states that 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. How will such adjustment be considered for calculation of incentive and/ or eligible committed investment? What impact would these have?  
The adjustment would be considered subject to provisions of relevant statutes and Accounting Standards- 18 and corresponding Ind-AS, as amended from time to time.
2. Clause 7.2.5 of the Operational guidelines provides that incentive applicable to selected applicant shall be computed as “net incremental sales of eligible product Rate of Incentive– Assume that the company is already manufacturing the eligible product in base year 19-20 from existing plant and machinery and continues to use the same for manufacture and sale thereof. Further investment is done in new plant and machinery for the same eligible product, but commercial production and sales take place in the year 2023-24. Meanwhile incremental sales requirement for existing plant for the eligible product continues and there the threshold requirement is met. Will the same be counted towards incentives given that that there is net incremental sales of eligible product (even if the same is not manufactured from new plant and machinery for the same eligible products)  
Yes, the interpretation is correct. However, year wise minimum cumulative investment criteria and incremental net sales criteria both have to be met by the Applicant and its Group Companies as per Appendix B of the Operational guidelines.
3. In case the eligible products are added to list later on i.e say in FY 2023-24 for secrecy or any other reason. What happens to the investment in P&M or R&D spends done pre the said year? So basically question is whether investment is also to be seen qua the product list submitted by the applicant or qua eligible products specified in the guidelines only?  
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.  
Once the change in product mix is approved, eligible investment made towards P&M or R&D (as defined in clause 2.15 of the operational guidelines) in respect of the newly approved product, made after 01.04.2020 can be considered under the scheme.
4. (a) Whether incentive will be available for an eligible product, manufactured in FY 2023-24 for the first time, provided the same has been approved in the Application. That is, threshold sale in FY 2022-23 for the said new product will be NIL and also the sales in the base year (FY 2019-20) for the said product will be NIL.  
(b) Also, if any eligible product which is not covered in Application but manufactured subsequently (say FY 2023-24), whether incentive will be available.  
(a) As per the Operational Guidelines, the first year for release of incentive is FY 2022-23. In the instant case, the incremental sale for FY 2022-23 will be considered as zero. Hence, the applicant won't be eligible for any incentive in the FY 2022-23.  
For FY 2023-24 (first year of manufacturing), the applicant may be eligible for incentive, subject to achievement of committed cumulative investment and threshold sales under the eligible product.  
As per Appendix B of the Operational Guidelines:  
“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 has to be greater than Rs. 50 crore in case of a Group A



participant, greater than Rs.10 crore in case of a Group B participant, greater than Rs.1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant.

For subsequent financial years i.e. from FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the approved eligible product of the previous financial year.”

In the instant case, the applicant does not have any sales under the eligible product in FY 2022-23. Hence, in line of the Operational Guidelines, the threshold sales for FY 2023-24 are to be considered at 7% growth over the first year’s threshold sales (as defined in the scheme) of Rs.50 Crore/ Rs.10 Crore/ Rs.1 Crore depending on the applicant’s group (A/ B/ C/ C-MSME). For subsequent years, the threshold sales shall be computed at 7% growth over actual sales.

(b) Yes.

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 during the tenure of the scheme with the prior approval of the DoP. However, this option may be exercised not more than 5 times during the tenure of the Scheme.

5. Clause 2.8 and 2.15 - Whether committed investment can be made in a related party/ new subsidiary and the incentive be claimed at the applicant entity level, basis consolidated revenue achieved by the applicant company?

As per the Operational Guidelines (read with Corrigenda/Addenda) both committed investment and threshold/ incremental sales must be achieved by Applicant and its Group Companies.

6. Can R&D expenditure made towards eligible products, which the applicant is not eventually able to sell during the tenure of the scheme, would be considered as eligible investment?

To be eligible for incentives, the applicant has to achieve both the Minimum Cumulative Investment and Threshold/ Incremental Sales as per Appendix B of the Operational Guidelines.

7. Is there any maximum limit of incentive which will be paid out in any year to an applicant? Or to all applicants in a Group?

The annual incentive allocation, vide clause 7.2 of the Operational Guidelines, shall be made for each participant by DoP within the total incentive allocation per participant fixed for the entire tenure of the scheme as stated in the approval letter. The participant shall be eligible to draw incentive within that annual allocation.

8. If we are making basket ABC and then if we will make basket XYZ where top line and bottom line are different - How will such aberrations be handled?

For being eligible for the incentive, the applicants have to meet threshold sales under the approved eligible products and minimum cumulative investments as per Appendix B. Further, the scheme also has a provision for change in eligible product subject to approval of DoP.

9. After submission of the documents in how many days incentive will be remitted?

Incentive will be released after careful examination of the claim application submitted by the selected applicant by the PMA and approval of DoP thereof.

10. As per clause 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of minimum cumulative investment for FY 2021-22 and invoked in case of FY 2021-22 is not achieved unless explicit permission is given by DoP. Are there any consequences if the Company fails to achieve the same in the subsequent years, other than losing out on the particular year incentives?

Clause 9.8 provides that if a selected applicant is found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc of the Scheme, or declines the offer of the approval under the Scheme at any stage, the envisaged incentive claim of such selected applicant shall be forfeited and the bank guarantee shall be invoked, if not released under para 9.6 and the offer letter issued shall stand cancelled. Need clarification on what would be covered under 'if it has not complied with notifications, orders, guidelines etc of the Scheme' – would not completing minimum cumulative investment in any subsequent year (after FY 2021-22) come under this reference.

As per clause 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of threshold investment of FY 2021-22 and shall be invoked in case of non-achievement of minimum cumulative investment of FY 2021-22.

If the selected applicant fails to achieve minimum cumulative investment (as defined in the Appendix B) in the subsequent years, it will not be eligible for incentive for that particular year.

Clause 9.8 states that applicants found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc. of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason. As such, clause 9.8 is not related to achievement/ non-achievement of minimum cumulative investment in any given year under the scheme.

11. A company which has applied under the earlier PLI Scheme for API/ KSM in 2020 but was not selected for whatever reasons. However, one of such APIs does flow into the formulation and gets covered under the eligible Product list under the new PLI Scheme of June 2021. In this case, whether the investment made in the API site to create such API capacity can be considered for calculating the Rs. 200 Crs per year investment from the Base Year (after 1-04-2020) as defined in this PLI Scheme of June 2021? For calculating the incremental sales as compared to the Base Year 2019-20, please confirm as to whether incremental sales of both Formulation and APIs of the eligible Products can be considered under the PLI Scheme of June 2021 or only incremental sales of Formulation would be considered?

Investment- If the API plant 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.

Sales- Only net incremental sales for eligible products would be considered.

12. Availment of complete incentive in a single year: Can an applicant invest the entire amount in a single financial year? If yes can such applicant avail the entire incentive permissible under the scheme per participant in the same year based on the incremental sales achieved?

Applicant may choose to invest as per business requirements either in stages or one go. Actual cumulative investment done by the applicant must meet the minimum cumulative investment criteria as defined in Appendix B of Operational Guidelines, for being eligible for incentives.

However, incentive can be claimed as per Appendix B Schedule and not at one go.

13. Group B applicant make investment as per limits prescribed for Group A: Can an applicant who is categorized as a Group B applicant as per the GMR, make an investment of INR 1000 crores and be eligible to claim maximum incentive of INR 1200 crores which is applicable to Group A participants. There is only the threshold which is prescribed for investment and no ceiling has been prescribed. Group B applicant may make an investment of Rs. 1000 crore, but maximum incentive ceiling for a Group B applicant is Rs.300 crore over the entire Scheme.

14. For disbursement of incentives no timeline mentioned with regard to approval from DoP, though PMA processes the application for claim within 60 days of receipt of application.

As per clause 7.3.7 of the Operational Guidelines, the PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to DoP. Disbursement of the incentive will be done subsequently.

15. As per para 9.6 of the operational guidelines, the bank guarantee shall be released upon achievement of minimum cumulative investment for FY 2021-22. What could be the possible consequences if the Company fails to achieve the same in the subsequent years?

As per clause 9.6 of the operational guidelines, bank guarantee shall be revoked in case the minimum cumulative investment for FY 2021-22 is not met. However, no specific penalty has been prescribed currently for failure to meet the subsequent investments. If committed investment criteria is not met in any year, incentive for that year shall not be granted. However, the applicant will not be restricted from claiming incentive for subsequent years, provided criteria of minimum cumulative investment and incremental sales are met for such subsequent years.

## J. Miscellaneous FAQs

1. **What if a product comes under price control and sales value is drastically reduced (formulations)?**  
There is no such provision in the Operational Guidelines for the same.
2. **The scheme has provisions around succession-in-interest, we request for clarification on how the new investment shall be calculated and PLI shall be disbursed to the entities formed after demerger of the undertaking as incremental investments and production shall be done in the two entities.**  
As per clause 12.3 of the operational guidelines, in case of a successor-in-interest, all Investment undertaken by the applicant to whom approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the DoP, as may be deemed appropriate.  
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.
3. **Clause 3 says Tenure of the Scheme is from FY 20-21 to FY 28-29. While 20-21 may have been factored as the investment of this year is also counted, but not sure why FY 28-29 is factored when the incentive period is 6 years from FY 22-23 to FY 27-28**  
As per clause 7.3.3 of the operational guidelines, claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, 75% of it shall be released and the remaining 25% shall be released after submission of final audited accounts of the Company.  
Accordingly, incentive claim for FY 2027-28 will be submitted by the applicant and processed by PMA/ DoP in FY 2028-29. Hence the tenure of the scheme is from Financial Year 2020-21 to Financial Year 2028-29.