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Indian APIs & Formulations for Global Healthcare

HIGHLIGHTS

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Vol. No. 52 **Issue No. 29** **01 to 07 August 2021**

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DoP issued: Updated and New FAQs on Pharma PLI Scheme - reg.

ATTENTION MEMBERS

DoP has issued 2 sets of FAQs in relation to the Pharma PLI scheme on the official website, updating the First FAQs issued previously on 1st July 2021 and 2nd set of FAQs covering certain new questions.

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 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. 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 in 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 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 the 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, Sl. 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**

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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.

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

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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 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.

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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.

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	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.

Draft New Drugs and Clinical Trials (Amendment) Rules, 2021 - reg.

NOTIFICATION G.S.R. 524(E), dated 2nd August, 2021

The following draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019 which the Central Government proposes to make, in exercise of the powers conferred bysub-section(1) of section 12 and sub-section(1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information fall persons likely to be affected there by and notice is here by given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No.434, C Wing, Nirman Bhavan, New Delhi-110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

(1) (1) These rules may be called the New Drugs and Clinical Trials (Amendment) Rules, 2021.

(2) They shall come into force on the date of their final publication in the Official Gazette.

(2) In the New Drugs and Clinical Trials Rules, 2019, in Eighth Schedule, in Form CT-03, -

(i) In para 1, the words, “Regulation of”, shall be omitted;

(ii) For the words, “Central Licensing Authority”, the words “Designated Registration Authority” shall be substituted.

F. No. X.11014/13/2021-DR

Dr. Mandeep K. Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: *The principal rules were published in the Gazette of India vide notification number G.S.R.227(E), dated the 19th March, 2019.*

In Lok Sabha & In Rajya Sabha

RAJYA SABHA

Boosting Vaccine Production in the Private Sector

Rajya Sabha Starred Question No.76

Shri Harnath Singh Yadav:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the action that has been taken by Government to boost the private sector to enhance the production of vaccines in the country such as Covishield and Covaxin so as to control the prevailing COVID-19 pandemic in the country; and

(b) whether it is a fact that Government has proposed to provide free vaccine to all citizens of the country, if so, the number of people who have been vaccinated in the country till date?

Answered on 27th July 2021

A. (a) & (b) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 76* FOR 27TH JULY, 2021

(a) The Government of India has taken many steps to augment the domestic manufacturing capacity of COVID-19 vaccines. The Department of Biotechnology (DBT), Ministry of Science & Technology, is implementing a scheme 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. Under this Mission, facility augmentation for production of Covaxin is being supported whereby M/s Bharat Biotech and 3 Public Sector Enterprises (PSEs) including M/s Haffkine Biopharmaceutical Corporation Ltd, Mumbai; M/s Indian Immunologicals Limited (IIL), Hyderabad; M/s Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; are being extended financial and technical support.

Additionally, technology transfer of Covaxin production to Consortium of partners including M/s Hester Biosciences and OmniBRx Biotechnologies Pvt. Ltd., led by, Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, is being facilitated by the Department of Biotechnology. These efforts are expected to enhance the production of Covaxin in the coming months.

Government of India has provided 100% advance payment against supply orders placed with domestic vaccine manufacturers before 22nd April 2021 to enable them to utilize these funds for capacity augmentation.

Government of India has also provided advance payment to one of the domestic vaccine manufacturer M/s Biological E for 'At-risk manufacturing' of COVID-19 vaccine.

Regulatory norms have been streamlined for approval of vaccines in India that have received Emergency Use License (EUL) by foreign regulators like FDA of United States, MHRA of United Kingdom, PMDA of Japan or WHO-EUL.

(b) As per 'Revised Guidelines for implementation of National COVID Vaccination Program', with effect from 21st June 2021, all 18+ years citizens irrespective of their income status are entitled to free vaccination at all government vaccination centres. As on 25th July 2021, a total of 34.04 crore persons have received at least one dose of COVID-19 vaccine and a total of 43.32 crore doses have been administered across Country.

The Minister of Health and Family Welfare
(Shri Mansukh Mandaviya)

COVID-19 Vaccine Booster Dose

Rajya Sabha Unstarred Question No.903

Shri Binoy Viswam

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has taken note of the fact that many countries are adopting an approach of vaccine booster shots to ensure protection against COVID-19 and its various strains;

(b) whether there is a need to take a booster dose of the vaccine after a certain period of time;

(c) if so, Government's plan for the same and how it is ensuring sufficient vaccine supply;

(d) whether Government has conducted any study on how long the COVID-19 vaccine is effective; and

(e) whether Government has developed a long term vaccine strategy plan for COVID-19?

Answered on 27th July 2021

A. (a) to (c): There are some media reports of some countries considering booster dose of Covid-19 vaccine. The National Technical Advisory Group on Immunization (NTAGI) and National Expert Group on vaccine administration for Covid (NEGVAC) are deliberating and considering scientific evidences related to dose schedule of Covid-19 vaccines. So far, no specific recommendation regarding Covid-19 vaccine booster dose has been made by NTAGI or NEGVAC. There are, at present no recommendation on booster dose from World Health Organization.

(d): The COVID-19 vaccines have been developed very recently, therefore, scientific evidence is still evolving globally regarding duration of protection.

(e): The Department of Biotechnology (DBT), Ministry of Science & Technology, is supporting the implementation of 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. Under the Mission, facility augmentation for production of Covaxin is being supported whereby Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad; Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; are being supported.

Additionally, technology transfer of Covaxin production to Consortium of partners including Hester Biosciences and OmniBRx Biotechnologies Pvt. Ltd., led by, Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, is being facilitated by the Department of Biotechnology. These efforts are expected to enhance the production of Covaxin in the coming months.

Government of India has also provided 100% advance to domestic vaccine manufacturers in respect of procurement order placed with them. These funds can be used by such manufacturers for their capacity augmentation.

Government of India has also provided advance to one of the vaccine manufacturer i.e M/s Biological E for 'At-risk manufacturing' of COVID-19 vaccine.

Regulatory norms have also been streamlined for approval of vaccines in India that have received Emergency Use License (EUL) by FDA of United States, MHRA of United Kingdom, PMDA of Japan or WHO-EUL.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Black-Marketing of Medical Resources During The Second Wave of COVID-19

Rajya Sabha Unstarred Question No.904

Shri Sanjay Singh

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government is aware of the black marketing of medical resources in the country during the second wave of COVID-19 where medicines, oxygen and other resources were being sold off at exorbitant prices; and

(b) if so, the steps taken by Government to curb such malpractices and action taken against such identified authorities?

Answered on 27th July 2021

A. (a) & (b): Health is a state subject, Government of India has provided the required technical support and has also supported the states through logistic and financial support to further strengthen the existing health infrastructure to tackle COVID-19 pandemic.

Some of the ongoing initiatives to further strengthen healthcare infrastructure include:

- With the intent to reduce the risk of cross infection to non-COVID patients as well as to maintain continuity of non-COVID essential health services in the country, a three-tier arrangement of dedicated COVID-19 health facilities [(i) COVID Care Center (CCC); (ii) Dedicated COVID Health Centre (DCHC) and (iii) Dedicated COVID Hospital (DCH)] has been implemented in the country.
- Government of India, to supplement the hospital facilities has roped in tertiary care hospitals under ESIC, Defence, Railways, paramilitary

forces, Steel Ministry etc. Further, many large temporary treatment facilities were established by DRDO to manage surge in COVID-19 cases in the country.

- The isolation bed capacity and ICU bed capacity which was only 10,180 and 2,168 before the first lockdown (as on 23rd March 2020) in being enhanced continuously and is currently at 18,21,845 isolation beds and 1,22,035 ICU beds (as on 20th July 2021).
- The daily liquid medical oxygen (LMO) supply, which was about 1292 MTs per day in February 2021 increased to a high of 8593 MTs in May 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants.
- Restrictions were imposed on industrial use of oxygen.
- A dynamic and transparent framework for allocation of medical oxygen in consultation with States/UTs and all the stakeholders such as relevant Ministries, manufacturers/suppliers of liquid oxygen etc. was prepared.
- Online digital solutions viz. Oxygen Demand Aggregation system (ODAS) and Oxygen Digital Tracking System (ODTS) have been developed to ascertain the demand for medical oxygen from all medical facilities and to track their transportation.
- To avoid wastage of medical oxygen, guidelines on rational use of oxygen were issued on 25th September 2020, and further revised and disseminated to States on 25th April 2021.
- 1,02,400 oxygen cylinders were procured in April and May of 2020 and distributed to States.

  Further orders for additional 1,27,000 cylinders have been placed on 21st April 2021, (54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type). Deliveries of the same have started and 24,207 (24,511 B-type and 8,893 D-type) cylinders have been delivered as on 7th July 2021. In addition, around 4962 B-type and 1895 D-type cylinders are in-transit.
- To generate oxygen at the health facility level, PSA plants are being established in hospitals, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country.
- Further, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, more than 18,000 Oxygen Concentrators have been allocated to various States.
- A COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID-19 management.
- A Drugs Coordination Committee (DCC) has been constituted as an institutional mechanism under Department of Pharmaceuticals for efficient decision making on all the issues with respect to COVID-19 related drugs including availability through inter-departmental consultations.
- Remdesivir is a patented drug, manufactured in India under voluntary licenses granted by Gilead Life Sciences USA (the patent holder) to 7 Indian pharmaceutical companies. Manufacturing capacity was augmented from 38 lakh vials per month to nearly 122 lakh vials per month. In addition, 40 additional manufacturing sites were approved by the CDSCO, thus increasing the manufacturing sites from 22 to 62.
- All States/UT and State Drugs Controllers have been requested to verify stock of the drug and check other malpractices and take effective steps to curb hoarding and black marketing of Remdesivir.
- Department of Pharmaceuticals and the Drug Controller General of India (DCGI) have actively coordinated with the industry to enhance availability of Amphotericin B through identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.
- Besides, the existing five manufacturers, DCGI had issued permissions to manufacturing / marketing of Amphotericin B Liposomal Injection to six additional firms.
- Ministry of Health & Family Welfare continues to provide technical guidance for managing various aspects of COVID-19. So far more than 150 guidelines/advisories/SoPs/plans have been provided to States/UTs. Taking note of ingress of COVID-19 pandemic in peri-urban and rural

areas, Ministry of Health & Family Welfare on 16th May 2021 issued an SOP on COVID-19 Containment & Management in Peri-urban, Rural & Tribal areas.

- Further COVID-19 treatment protocols and advisories both for adults as well as pediatric age groups were issued and widely disseminated to promote rational use of drugs and oxygen.
- Union Ministry of Health and Family Welfare has requested all States/UTs health officials and licensing authorities through advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against any black-marketing by conducting special drives for monitoring and investigation.
- Enforcement actions like seizures, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

ICMR ROYALTY IN COVAXIN

Rajya Sabha Unstarred Question No.908

Dr. Narendra Jadhav

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it is a fact that ICMR holds the royalty to Covaxin jointly with Bharat Biotech;

(b) if so, the details of the MoU signed between ICMR and Bharat Biotech;

(c) if not, whether it is a fact that ICMR is charging 5 per cent royalty on each sale of Covaxin;

(d) if so, whether ICMR has any plans to drop royalty payment requirement so that price of Covaxin may be reduced;

(e) if so, the details thereof; and

(f) if not, the reasons therefor?

Answered on 27th July 2021

A. (a) to (c) Yes. Key Terms of the Memorandum of Understanding (MoU) between ICMR and Bharat Biotech for development of an indigenous COVID-19 vaccine are as follows:

i. Collaboration for development of COVID-19 inactivated whole cell Vaccine.

ii. ICMR to provide well characterized virus strain for vaccine development.

iii. Bharat Biotech International Limited (BBIL) to develop the final vaccine formulation.

iv. Non-Exclusive License granted to commercialize product within 2 year period.

v. Payment of initial seed money of Rs. 5 Lakhs for transfer of inactivated virus strain to be paid by Licensee as one-time payment.

vi. Royalty Obligations - 5% on Net Sales, to be remitted on half yearly basis.

vii. IP to be jointly owned by ICMR and BBIL.

viii. It has been agreed that COVID vaccine will come in the joint name of ICMR and Bharat Biotech.

ix. ICMR logo to be put on the product.

x. Bharat Biotech will supply vaccines free of cost for the clinical trial.

xi. BBIL had agreed to provide vaccine at a reasonable and negotiated price to ICMR as well as all Central and State Government bodies/ affiliates etc. as and when the vaccine is available for use.

xii. BBIL to prioritize in-country supplies over the export of the vaccine, as and when the vaccine is available.

(d) to (f): No. This clause is governed by the MoU executed between ICMR and Bharat Biotech for development of Covaxin.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Permission for usage of Covid Vaccines In India

Rajya Sabha Unstarred Question No.916

Shri Abdul Wahab:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the number of companies that have sought permission from Government to use COVID- 19 vaccines in India;

(b) whether Pfizer has sought permission from Government to use its COVID-19 vaccine in India;

(c) whether it is a fact that Government has not given permission to COVID-19 vaccine manufactured by Pfizer; and

(d) if so, the reasons therefor?

Answered on 27th July 2021

A. (a) to (d): As per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organization (CDSCO) has granted permissions to following five COVID-19 vaccines for restricted use in emergency situation:

1. ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (Covishield) manufactured by M/s Serum Institute of India Pvt., Ltd., Pune.
2. Whole Virion Inactivated Corona Virus Vaccine (Covaxin) manufactured by M/s Bharat Biotech International Limited, Hyderabad.
3. Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) manufactured by M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi.
4. Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] imported by M/s Dr. Reddy's Laboratories Ltd, Hyderabad.
5. mRNA-1273 COVID-19 vaccine (Moderna) imported by M/s Cipla Limited, Mumbai.

CDSCO had received an application from M/s Pfizer for grant of permission to import its COVID-19 vaccine in the country on 04.12.2020. The proposal was deliberated in the Subject Expert Committee (SEC) of COVID in its meeting held on 03.02.2021. The committee noted certain concerns with the data filed by Pfizer, however in the meantime, Pfizer withdrew its application on 05.02.2021. Thereafter, firm has not as yet applied for obtaining the import permission for its Covid vaccine.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Efforts towards Recognition for Covaxin in Foreign Countries

Rajya Sabha Unstarred Question No.917

Shri Abdul Wahab:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it has come to the notice of Government that Covaxin used in India as COVID vaccine is not recognised by many countries; and

(b) the efforts that have been made by Government to resolve this issue?

Answered on 27th July 2021

A. (a): Yes, Government of India is aware that Covaxin at present is not part of WHO Emergency Use Listing (EUL).

(b): All documents required for Emergency Use Listing (EUL) have been submitted by Bharat Biotech International Ltd. to WHO as of 9th July 2021. The review process by WHO has commenced. WHO usually takes upto six weeks to decide on Emergency Use Listing (EUL) submissions.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Non Utilisation of Vaccination Manufacturing Units

Rajya Sabha Unstarred Question No.923

Shri P. Wilson:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state

(a) reasons for not utilising three vaccination manufacturing units at HLL Biotech, Chengalpattu,Tamil Nadu , BCG Vaccine Laboratory, Chennai and Pasteur Institute of India, Coonoor, Tamil Nadu for manufacturing of COVID-19 vaccines despite requests from Chief Minister of Tamil Nadu;

(b) details of COVID-19 vaccines distributed to all States, brand-wise, and total expenditure incurred in purchase of vaccines by Government till end of June 2021, brand wise and cost of each vial for each brand; and

(c) steps taken by Government to get immediate EUL Clearance from WHO for Covishield and Covaxin so as to enable Indian citizens to move freely abroad?

Answered on 27th July 2021

A. (a): COVID-19 vaccine is a viral vaccine which requires complex manufacturing processes and

even Biosafety Level III (BSL-III) facility, depending on the process adapted for the manufacture of the vaccine. BCG Vaccine Laboratory, Chennai and Pasteur Institute of India, Coonoor does not have the BSL-III facility as such they are not in a position to manufacture Covid-19 vaccines.

HLL Lifecare Limited has invited expression of interest from vaccine/Pharmaceutical Manufactures for use of HBL's existing facilities at Integrated Vaccine Complex (IVC), Chengalpattu. Presently the Government is in dialogue with the interested companies for utilization of HBL Chengalpattu.

(b): The COVID-19 vaccine supplied to States/ UTs free of cost by Government of India, direct procurement by States/UTs and procurement by private hospitals, is placed at Annexure.

A total of INR 9725.15 crore have been spent so far on the COVID-19 vaccination programme including procurement of vaccines and operational cost for vaccination.

As per the latest Supply Order, Government of India is purchasing Covishield (exclusive of taxes) @ Rs. 205 per dose and Covaxin (exclusive of taxes) @ Rs 215 per dose.

(c): Covishield vaccine is already a part of WHO Emergency Use Listing (EUL). All documents required for Emergency Use Listing (EUL) have been submitted by Bharat Biotech International Ltd. In respect of its Covaxin vaccine to WHO as of 9th July 2021. WHO usually takes upto six weeks to decide on Emergency Use Listing (EUL)

Annexure

COVID-19 vaccine supplied to States/UTs, vaccine-wise

(as on 25th July 2021)

Sr. No.	States/UTs	Covishield	Covaxin	Total
1	A&N Islands	3,16,500	-	3,16,500
2	Andhra Pradesh	1,68,35,010	32,45,610	2,00,80,620
3	Arunachal Pradesh	11,36,250	-	11,36,250
4	Assam	86,04,220	15,85,630	1,01,89,850
5	Bihar	2,10,43,640	25,11,930	2,35,55,570
6	Chandigarh	7,78,330	-	7,78,330
7	Chhattisgarh	1,04,75,860	13,43,720	1,18,19,580
8	Dadra and Nagar Haveli	2,96,390	-	2,96,390
9	Daman and Diu	3,12,990	-	3,12,990
10	Delhi	89,18,510	26,13,370	1,15,31,880
11	Goa	20,71,950	35,980	21,07,930
12	Gujarat	2,71,56,350	35,71,500	3,07,27,850
13	Haryana	96,33,870	17,49,250	1,13,83,120
14	Himachal Pradesh	49,44,170	5,000	49,49,170
15	Jammu and Kashmir	54,29,350	2,45,910	56,75,260
16	Jharkhand	79,70,460	14,64,060	94,34,520
17	Karnataka	2,60,56,750	37,77,530	2,98,34,280
18	Kerala	1,64,16,690	17,77,620	1,81,94,310
19	Ladakh	3,24,560	-	3,24,560
20	Lakshadweep	96,580	-	96,580
21	Madhya Pradesh	2,53,48,600	34,19,900	2,87,68,500
22	Maharashtra	3,91,71,860	59,66,190	4,51,38,050
23	Manipur	13,86,270	-	13,86,270
24	Meghalaya	12,61,380	-	12,61,380
25	Mizoram	10,48,270	-	10,48,270
26	Nagaland	8,44,420	-	8,44,420
27	Odisha	1,34,12,900	21,13,710	1,55,26,610
28	Puducherry	7,99,980	-	7,99,980
29	Punjab	81,36,850	12,25,120	93,61,970
30	Rajasthan	2,63,30,450	33,68,990	2,96,99,440
31	Sikkim	8,03,220	-	8,03,220
32	Tamil Nadu	1,83,78,470	31,93,450	2,15,71,920
33	Telangana	1,17,80,450	46,16,010	1,63,96,460
34	Tripura	31,10,440	70,520	31,80,960
35	Uttar Pradesh	4,04,57,930	60,32,840	4,64,90,770
36	Uttarakhand	51,15,800	4,67,510	55,83,310
37	West Bengal	2,49,83,460	35,25,970	2,85,09,430
Total		**39,11,89,180**	**5,79,27,320**	**44,91,16,500**

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Extending Gap Between Covishield Doses

Rajya Sabha Unstarred Question No.899

Shri Mallikarjun Kharge:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it is a fact that several members of the National Technical Advisory Group on Immunisation (NTAGI) have claimed that there was not enough

data for them to make a recommendation on extending the gap between Covishield doses;

(b) if so, the reason based on which the gap was extended by Government; and

(c) if not, the details of the data that was presented before the NTAGI based on which the gap was extended?

Answered on 27th July 2021

A. (a): (a) to (c): The Covid Working Group of National Technical Advisory Group on Immunization (NTAGI) recommended extension of the gap between the first & second doses of Covishield vaccine to 12-16 weeks based on available scientific evidence particularly from the United Kingdom as well as WHO global guidance. This recommendation has been considered & also recommended by the National Expert Group on Vaccine Administration for Covid-19 (NEGVAC).

The Ministry of Health & Family Welfare has accepted this recommendation for extension of the gap between the first and second doses of Covishield vaccine to 12-16 weeks.

The relevant recommendation of the Covid Working Group of NTAGI to increase the gap between Covishield doses has been taken based on scientific evidence in a transparent manner. No dissent was raised by any member in the said meeting of NTAGI regarding the said recommendation.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Vaccine Orders Placed with Foreign Manufacturers

Rajya Sabha Unstarred Question No.872

Shri Kapil Sibal:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the detailed timeline of the COVID-19 vaccines ordered by Government so far from various manufacturers;

(b) the details of vaccines procured by Government so far;

(c) whether orders have been placed with foreign vaccine manufacturers, if so, the details of manufacturers and the number of doses; and

(d) by when the entire adult population is expected to be vaccinated?

Answered on 27th July 2021

A. (a) & (b): The details of communication made by Government of India to HLL, the procurement agency, for procurement of COVID-19 vaccines is as under:

Date of communication to HLL	Vaccine quantity (in crore)		
	Covishield doses	Covaxin doses	Total doses
10th January 2021	1.1	0.55	1.65
3rd February 2021	1.0	0.45	1.45
10th February 2021	1.5	-	1.5
24th February 2021	2.0	-	2.0
12th March 2021	10	2	12
5th May 2021	11	5	16
16th July 2021	37.5	28.5	66
TOTAL	**64.1**	**36.5**	**100.6**

(c): Government of India has constituted a team of officials to deal with various issues related to procurement of COVID-19 vaccine from foreign manufacturers. This team is in continuous dialogue with foreign manufacturers.

(d): The COVID-19 vaccination is an ongoing and dynamic process, which is being guided by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) on the basis of concurrent scientific evidence. It is expected that eligible beneficiaries aged 18 years and above will be vaccinated by December 2021.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Extension of Gap Between Two Doses of Astrazeneca Vaccine

Rajya Sabha Unstarred Question No.889

Shri Shaktisinh Gohil:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has doubled the gap between the two doses of the Astra Zeneca COVID-19 vaccine saying that the extended gap was recommended by the National Technical Advisory Group on Immunisation (NTAGI), based on real-life evidence mainly from Britain;

(b) whether Government is aware that three of the 14 members of the NTAGI have said that the body did not have enough data to make such a recommendation; and

(c) if so, the reasons for the miscommunication?

Answered on 27th July 2021

A. (a): The COVID Working Group of National Technical Advisory Group on Immunisation (NTAGI) recommended extension of the gap between the first and second doses of Covishield vaccine to 12-16 weeks based on available scientific evidence particularly from the United Kingdom as well as WHO global guidance. This recommendation has been considered and also recommended by the National Expert Group on Vaccine Administration for Covid-19 (NEGVAC).

The Union Ministry of Health and Family Welfare has accepted this recommendation for extension of the gap between the first and second doses of Covishield vaccine to 12-16 weeks.

(b) & (c): The relevant recommendation of the Covid working group of NTAGI to increase the gap between Covishield doses has been taken based on scientific evidence in a transparent manner. No dissent was raised by any member in the said meeting of NTAGI regarding the said recommendation.

The Minister of State in The Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

LOK SABHA

Manufacture of Fake Medicine

Lok Sabha Unstarred Question No. 1239

Shri Manoj Tiwari:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has any proposal to make strict laws regarding the manufacture of fake medicines which was very evident during the second wave of the COVID-19 pandemic in the country;

(b) if so, the details thereof;

(c) if not, the reasons therefor; and

(d) the details of its impact on the pharma sector?

Answered on 27th July 2021

A. (a) to (d): As per Central Drugs Standard Control Organisation (CDSCO), manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 made there under through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments.

Manufacturer/Licensees are required to comply with all the condition of license and follow Good Manufacturing Practices (GMP) as prescribed in Schedule M to Drugs Rules to ensure that the drugs manufactured by them are safe and of standard quality. The State Licensing Authorities are empowered to take action against any violation of the conditions of licenses.

Further, in order to harmonize the good manufacturing Practices (GMP) in line with WHO guidelines, Draft Rules have been published vide GSR No 999 (E) Dated 05.10.2018 for amendment in Schedule M of the Rules for ensuring quality of drugs manufactured in the Country.

Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

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Statutory Compliance Calendar for August 2021

S. No.	Statue	Purpose	Compliance Period	Original date	Extended Date	Event Details
1.	Income Tax	TDS/TCS Liability Deposit	Jul-21	7-Aug-21	7-Aug-21	Due date of depositing TDS/TCS liabilities for previous month.
2.	Income Tax	TDS/TCS Liability Deposit	Jul-21	7-Aug-21	7-Aug-21	Due date of depositing TDS/TCS liabilities for the period April to June for quarterly deposit of TDS under section 192, 194A, 194D or 194H
3.	GST		Jul-21	10-Aug-21	10-Aug-21	GSTR 7 is a return to be filed by the persons who is required to deduct TDS (Tax deducted at source) under GST.
4.	GST		Jul-21	10-Aug-21	10-Aug-21	GSTR-8 is a return to be filed by the e-commerce operators who are required to deduct TCS (Tax collected at source) under GST.
5.	GST		July, 2021	11-Aug-21	11-Aug-21	1. GST Filing of returns by registered person with aggregate turnover exceeding INR 5 Crores during preceeding year. 2. Registered person, with aggregate turnover of less then INR 5 Crores during preceeding year, opted for monthly filing of return under QRMP
6.	GST		July, 2021	13-Aug-21	13-Aug-21	Invoice furnishing facility for July, 2021 is available for registered person with turnover less than INR 5 Crores and opted for quarterly filing of return.
7.	GST		July, 2021	13-Aug-21	13-Aug-21	Due Date for filing return by Input Service Distributors.
8.	Income Tax	TDS Certificate	Jul-21	14-Aug-21	14-Aug-21	Due date for issue of TDS Certificate for tax deducted under section 194-IA, 194-IB and 194M in the month of April, 2021
9.	Labour Law	Providend Fund / ESI	Jul-21	15-Aug-21	15-Aug-21	Due Date for payment of Provident fund and ESI contribution for the previous month.

10.	Income Tax	TDS Certificate	Q1 FY 2021-22	15-Aug-21	15-Aug-21	Quarterly TDS certificate (in respect of tax deducted for payments other than salary) for the quarter ending June 30, 2021
11.	Income Tax	Furnishing Form 24G	Jul-21	15-Aug-21	15-Aug-21	Due date of furnishing of Form 24G by an office of the Government where TDS/TCS for the month of July, 2021 has been paid without the production of a challan
12.	GST		July, 2021	20-Aug-21	20-Aug-21	Due Date for filling GSTR - 3B return for the month of July, 2021 for the taxpayer with Aggregate turnover exceeding INR 5 crores during previous year
13.	GST		Jul-21	20-Aug-21	20-Aug-21	GSTR-5 to be filed by Non-Resident Taxable Person for the previous month.
14.	GST		Jul-21	20-Aug-21	20-Aug-21	GSTR-5A to be filed by OIDAR Service Providers for the previous month.
15.	GST		July, 2021	22-Aug-21	22-Aug-21	Due Date for filling GSTR - 3B return for the month of July, 2021 for the taxpayer with Aggregate turnover upto INR 5 crores during previous year and who has opted for monthly filing of GSTR-3B
16.	GST		July, 2021	24-Aug-21	24-Aug-21	Due Date for filling GSTR - 3B return for the month of July, 2021 for the taxpayer with Aggregate turnover upto INR 5 crores during previous year and who has opted for monthly filing of GSTR-3B
17.	GST	GST Challan payment if no sufficient ITC available	Jul-21	25-Aug-21	25-Aug-21	GST Challan Payment for taxpayer, with aggregate turnover of less than INR 5 Crores during preceeding year, who has opted for quarterly filing of returns.
18.	Income Tax		Jul-21	30-Aug-21	30-Aug-21	Due date for furnishing of challan-cum-statement in respect of tax deducted under section 194-IA, 194-IB, 194M for the month of July, 2021

19.	Income Tax	Payment of tax under vivad se vishwas scheme		30-06-2021	31-Aug-21	Vivad se Vishwas Scheme - Settling tax disputes between individuals and the income tax department. Payment under this scheme last date was extended to 30th June, 2021wihtout late fee (vide Notification S.O. 1704 (E), dated 27-04-2021), it is further extended from 30th June, 2021 to 31st August, 2021without additional charge (vide Circular no. 12/2021, dated 25-06-2021)
20.	Income Tax	Filing of declaration in Form 15G/15H	Q1 FY 2021-22	15-Jul-21	31-Aug-21	Upload the declarations received from recipients in Form No. 15G/15H during the quarter ending June, 2021. The due date for uploading declarations has been extended from July 15, 2021 to August 31, 2021 vide Circular no. 12/2021, dated 25-06-2021
21.	Others			1st April, 2021 onwards	01-04-2021 onwards	MSMEs registrated prior to 30th June 2020, there MSME registration shall remain valid only up to 31st March, 2021, i.e., after this date it is mandatory for each and every enterprise to register itself on Udyam portal.
22.	GST	GST return for pending Period-Amensty Scheme	July, 2017 to April, 2021	01.6.2021 to 31.08.2021	31-Aug-21	Filing of Pending GST return with reduced penalty under Amensty Scheme
23.	MCA	All forms forms that are to be filed between the period of 1st April 2021 and 31st July 2021	FY 2020-21	01.04.2021 to 31.07.2021	31-Aug-21	MCA issued a notification stating that the forms that are to be filed between the period of 1st April 2021 and 31st July 2021 can be filed by 31st August 2021.

**Note 1: Not Opting for QRMP Scheme- Due Date for filling GSTR - 3B with Annual Turnover up to 5 Crore in State 1 Group (Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana, Andhra Pradesh, Daman & Diu and Dadra & Nagar Haveli, Puducherry, Andaman and Nicobar Islands, Lakshadweep)*

***Note 2: Not Opting for QRMP Scheme- Due Date for filling GSTR - 3B with Annual Turnover up to 5 Crore in State 2 Group (Himachal Pradesh, Punjab, Uttarakhand, Haryana, Rajasthan, Uttar Pradesh, Bihar, Sikkim, Arunachal Pradesh, Nagaland, Manipur, Mizoram, Tripura, Meghalaya, Assam, West Bengal, Jharkhand, Odisha, Jammu and Kashmir, Ladakh, Chandigarh, Delhi).*

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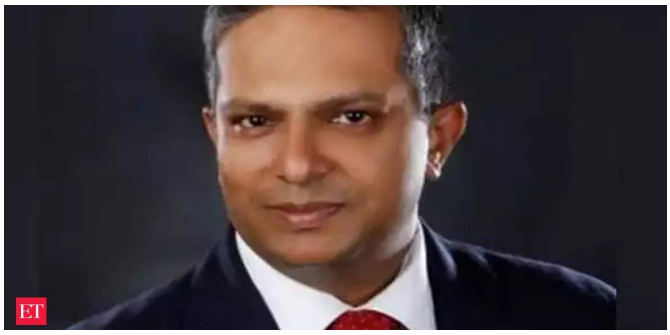
Focussing on volume led growth, not price led growth: Lal Path Labs



This quarter saw us serving 7.1 million patient visits, and of this about 11.4 lakh RTPCR tests were conducted. This was possible because of our large pan India network of laboratories and collection centres which have now been tech enabled, tells BharathUppiliappan, CEO, Dr Lal Path Labs, in an interview with ET Now.

Could you talk more about your Q1 earnings, especially the segmental breakup between Covid and non-Covid?

Q1 was characterised by two events; one was a very low base of last year because of the nationwide lockdown and second was a very high instance of Covid-19 infection in the April and May months of this year. This led us to record a revenue of about 607 crores. Yes, there was a lot of Covid business as well which came in this quarter but the good news is that our non-Covid revenues also grew about 3% sequentially vis-à-vis the last quarter of the last financial year. So, on the whole, we are very happy with what we have achieved on the non Covid side as well. This quarter saw us serving 7.1 million patient visits, and of this about 11.4 lakh RTPCR tests were conducted. This was possible because of our large pan India network of laboratories and collection centres which have now been tech enabled to be able to serve the patients in a very seamless fashion.

We look forward to strengthening our south and west business. We have announced a launch of a new reference lab at a pilot phase in Bengaluru this quarter and we have started off with new six satellite labs in the region across six different cities. That is something which we are trying to build upon as we go forward into the future. So overall, this quarter was very operationally intense, there was a very big surge in the Covid testing volumes and this led a lot of operational stress on the system with a lot of home collection requests being made, material shortage etc, but the team did a good job of overcoming all these challenges to deliver a record number of 607 crores.

How do you expect things to normalise going ahead, the Covid business will of course fall so what should be the run rate?

As you know that, we have always been talking of our focus on the non Covid business– and Covid only being an add-on service to the nation. So, in this context, as I said, our non Covid revenues grew 3% and we would like to continue this tempo and build a non Covid business across the country. We look forward to delivering coming back to normal rate of growth on the non Covid side as well. So non Covid is really the focus of what we would like to do and Covid is an add-on to serve the nation.

Will the growth in volumes actually continue if you see going ahead especially led by pan India expansion?

Our overall focus has been a volume led growth, not a price led growth. Yes, we try and optimise the mix at various points of times but our real focus is to drive the volumes up and be able to generate superior rate of growth vis-à-vis the market. We also see our south, west and east businesses skipping up now and as we expand into tier-2, tier-3, tier-4 cities even in the rest of north region, we are seeing a huge traction for our brand, our medical excellence and service excellence programs. Our focus is going to be volume led and that is what we are trying to put our network of labs and collection centres with technology so that we are able to handle and service the patients well.

Source : Negnews, ET Healthworld.com, 03.08.2021

Indian pharmaceutical sector back on track

The pharmaceutical industry holds a key position in tackling this worldwide Covid-19 pandemic that has left a deep impact on the Indian economy. Globally, the Indian pharmaceutical sector also holds a key position. According to IBEF, Indian pharmaceutical sector supplies over 50% of global demand for various vaccines. It also states that India is the largest provider of generic drugs globally. The pandemic has provided an outlandish opportunity to the Indian pharma industry to play a decisive role in the global market and rediscover itself – at the same time.

According to Indian Economic Survey 2021, the pharmaceutical industry is currently valued at $41.7 billion. India's domestic pharmaceutical market is estimated at $ 41 billion in 2021 and likely to reach $ 65 billion by 2024 and further expand to reach $ 120-130 billion by 2030. According to one estimate, already 2.7 million jobs have been created in the Indian pharma sector due to its growth.

In a recent virtual workshop organised by the Union Ministry of Health and Family Welfare (MoHFW), Department of Biotechnology (DBT), Ministry of Science and Technology, World Health Organisation (WHO), JSS Academy of Higher Education and Research, Mysuru (JSS AHER), AMTZ and Indian Pharmaceutical Alliance (IPA), speakers highlighted the need of strengthening the capacities of IVDs-medical devices manufacturing facilities to meet current global best practices and sharing global practices to promote availability and access to quality medical products. Enhancing availability of quality pharmaceutical products for all was also an important theme of discussion in the backdrop of the pandemic.

According to Flitch Ratings, Indian pharmaceutical companies' sales will grow robustly in the financial year ending March 2022 (FY22) as sales normalise in categories affected by the pandemic in the previous year. It also expects sales of drugs used to treat acute medical conditions and elective procedures to continue to recover in FY22. Sales in these categories fell in FY21 as travel restrictions reduced doctor visits and hospitals prioritised Covid-19 treatment over elective procedures.

The crisis over the vaccination process may see a significant improvement because India expects to receive three to four million doses of the Pfizer and Moderna Covid-19 shots through the COVAX facility by August. The country has so far administered 358.1 million vaccine doses - the most in the world after China - giving at least one dose to 31% of its estimated adult population of 944 million. Before it was shaken by the second wave, India had donated or sold more than 66 million doses of Covid-19 shots. According to experts, India needs to administer 10 million doses a day to achieve its aim of immunising all adults by December.

According to a report, the source of Active Pharmaceutical Ingredients (APIs) is a crucial part of the pharma industry's strategic plan to combat the Covid-19 pandemic. The majority of APIs for generic drug manufacturing across the globe are sourced from India, which also supplies approximately 30% of the generic APIs used in the US. However, Indian manufacturers rely heavily on APIs from China for the production of their medicine formulations, procuring around 70% from China, the top global producer and exporter of APIs by volume. The current dependency of Indian pharmaceutical companies on Chinese APIs is a serious concern for national health security, prompting the Indian government to set up a taskforce to review the internal API sector. India can reduce its dependency on imports only if it manufactures APIs/intermediates efficiently and sustainably. For this to happen, the government's intervention and support are crucial. As a step towards self-dependence, the Indian government initiated an `9,940 crore package in March 2020 to boost domestic production and exports of bulk drugs. Within this, the government approved the setting up of three bulk drug parks costing `3,000 crores and an `6,940-crore production-linked incentive (PLI) package.

Source :Saptarshi Deb, Business Economics, 16-31 July 2021

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4 more Indian pharma firms expected to start vaccine production by Oct-Nov: Health Minister

The government expects that by October-November, four more Indian pharmaceutical companies will start production of indigenous vaccines that will help meet the domestic demand, Health minister said.

New Delhi: Union Health Minister MansukhMandaviya on Tuesday said in Parliament that four more Indian pharma firms are expected to start anti-coronavirus

vaccine production by October-November that will accelerate the inoculation drive. During the Question Hour in the RajyaSabha, Mandaviya said India has administered 47 crore doses of vaccine so far and the Centre is making efforts to inoculate the entire country at the earliest.

Even 7 to 9 per cent of the doses that remain unutilised by private hospitals are being used by the government vaccination centres, he added.

Mandaviya was speaking amid a din in the house over the Opposition's demand for a discussion on the Pegasus issue and the farm laws.

"Vaccination drive is going on smoothly... It will get more accelerated in the coming days with the ramping up of production by four more Indian companies," the minister said.

The government expects that by October-November, four more Indian pharmaceutical companies will start production of indigenous vaccines that will help meet the domestic demand, he said.

Biologicals E and Novartis vaccines will also be available in the market in the coming days, while ZydusCadila will soon get an emergency-use nod from an expert committee, the Union Health Minister said

At present, two companies (Bharat Biotech and Serum Institute) are supplying the vaccine to the government. Sputnik vaccine is also available and production of which has begun, he added.

To a query by BJD member Amar Patnaik about the vaccine rollout plan for 12-18-year-old and the need for a third or fourth dose, Mandaviya said, "The government's target is to vaccinate the entire population at the earliest and constant efforts are being made to achieve this."

Unlike BCG (bacilleCalmette-Guerin) and polio vaccines that came to India much later after its launch in other parts of the world, the vaccine against coronavirus was made available in India at the same time in the world due to the efforts of the NarendraModi government, he said

The prime minister took steps, supported scientists and companies to ensure vaccines were available in the country at the earliest, the minister said.

"Thus vaccination drives began in India which has administered 47 crore doses so far, the maximum in the world. We are going to accelerate it further in the coming days," he said.

Responding to BJP member Susheel Kumar Modi's query on the government's plan to reduce the vaccine quota to private hospitals, the minister said it was not necessary as the unused vaccine quota of the private hospitals is taken by the government.

"In a month, we saw seven to nine per cent unused vaccines by private hospitals. So, we decided to take those unutilised doses in the government quota. Therefore, it is not necessary to reduce the quota for the private. The vaccination is happening smoothly," he said.

The Centre is buying 75 per cent of the vaccine produced to give free jabs to people, while 25 per cent is allocated for the private sector, the health minister added.

Source: PTI, 03.08.2021(ET Healthworld.com)

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Monthly production capacity of Covishield projected to increase to 120 million doses, Covaxin to 58 million doses: Minister

"As communicated by the manufacturers, the monthly vaccine production capacity of Covishield is projected to be increased from 110 million doses per month to more than 120 million doses per month and the production capacity of Covaxin is projected to be increased from 25 million doses per month to around 58 million doses per month," Union health minister said.

New Delhi: The monthly production capacity of Covishield is projected to be increased to more than 120 million doses and of Covaxin to around 58 million doses by December, the government told RajyaSabha on Tuesday, citing information from the COVID-19 vaccine manufacturers. Union Health Minister MansukhMandaviya was responding to a question on the current capacity to manufacture Covaxin and Covishield in the country, and the expected capacity going forward from August to December 2021.

"As communicated by the manufacturers, the monthly vaccine production capacity of Covishield is projected to be increased from 110 million doses per month to more than 120 million doses per month and the production capacity

of Covaxin is projected to be increased from 25 million doses per month to around 58 million doses per month," the minister said in a written reply.

Further, the Department of Biotechnology under the Ministry of Science and Technology has launched 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'.

The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a public sector undertaking (PSU) of the Department of Biotechnology, the reply stated.

Under the Mission, facility augmentation of Bharat Biotech and one state public sector enterprise and 2 central public sector enterprises (PSEs) -- Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat ImmunologicalsBiologicals Limited (BIBCOL), Bulandshahr -- for production of Covaxin have been supported.

In addition, technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC) of Department of Science and Technology, Government of Gujarat, has also been facilitated, the reply said.

Further, the Centre has also extended financial assistance to one of the domestic manufacturers for 'At-risk manufacturing', advance payment against the supply orders placed with Serum Institute of India and Bharat Biotech, besides streamlining regulatory norms for approval of vaccines, the reply added.

Source : ET Healthworld.com, PTI, 03.08.2021

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Covaxin output set to rise; govt hopes to meet 135 crore- dose goal

NEW DELHI: Indian Immunologicals Limited is likely to start supply of an additional 2 million doses of Covaxin from August-September, whereas Bharat Biotech's Ankleshwar facility is likely to add 6 million doses over next few months, the government said on Tuesday, adding it is hopeful of achieving the roadmap given for 135 crore doses between August-December.

Bharat Biotech is currently supplying around 2 crore doses of Covaxin per month, which is projected to increase to around 2.5 crore doses in August. Covaxin supplies faced a slowdown as its new manufacturing facility in Bengaluru with a large-scale fermentation plant facing initial glitches during standardisation of first few batches in June-July, resulting in delays in ramping up supplies.

According to officials, the issues have been resolved and supplies have started from the factory. "The quantum jump in Covaxin supplies will come from Bharat Biotech's Bengaluru facility. This has a large size reactor and system established by them and the contribution of supplies have started coming," NitiAayog's member (health) Dr V K Paul said.

In a written response in Parliament, health minister Mansukh Mandaviya said between August and December, the monthly vaccine production capacity of Covishield is projected to increase to over 120 million doses from 110 million doses, whereas that of Covaxin is projected to increase to 58 million doses from 25 million doses. The projections were given based on information shared by vaccine manufacturers. Apart from IIL, the two other PSUs — Haffkine Biopharmaceutical Corporation and BIBCOL — which received government support to manufacture Covaxin — are expected to supply the jab by December this year, Paul said. So far, the government has provided nearly 50 crore doses, of which around 47.52 crore were administered across the country till Monday.

The average daily vaccination increased to 43.41 lakh doses in July, from 39.9 lakh in June and 19.9 lakh in May.

Source: SushmiDey, TNN, 04.08.2021

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India's Remdesivir production capacity increased to 122.49 lakh vials per month in June: Govt

In order to substantially augment the production of Remdesivir, the Drugs Controller General of India granted expeditious approval to 40 new manufacturing sites of licensed manufacturers of the drug

New Delhi, India's production capacity of Remdesivir increased from 38.8 lakh vials per month in mid-April to 122.49 lakh vials per month in June 2021, and as on date, there is no shortage of the antiviral drug in any state or union territory, the Rajya Sabha was told on

Tuesday. Shortages of Remdesivir injections in the market were noticed in April and May 2021 due to a sudden surge in the demand for the drug for managing COVID-19 patients, Union Health Minister Mansukh Mandaviya said in a written reply.

In order to substantially augment the production of Remdesivir, the Drugs Controller General of India granted expeditious approval to 40 new manufacturing sites of licensed manufacturers of the drug, he said.

"This led to an increase in the number of Remdesivir manufacturing sites from 22 in mid-April 2021 to 62 at present. The domestic production capacity of Remdesivir increased from 38.8 lakh vials per month in mid-April to 122.49 lakh vials per month in June 2021," the minister said.

Further, in order to supplement the availability of Remdesivir manufactured in the country, the export of Remdesivir injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from April 11, 2021.

The Department of Pharmaceuticals (DoP) and the Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for the allocation of available stocks of Remdesivir to all states and UTs in order to mitigate shortage and to ensure a fair and equitable distribution across the country.

The MoHFW has also supplied around 29 lakh Remdesivir vials free of cost to states and UTs.

"As on date, the demand of Remdesivir has come down considerably and the demand-supply gap has reversed, whereby supply is much more than the demand. Accordingly, Remdesivir was moved from Prohibited to Restricted Category of Exports on June 14, 2021," Mandaviya said.

"Guidelines for Buffer Stock Management of Covid-19 Drugs" have been issued to states and UTs and they have been advised to procure and maintain buffer stocks of Remdesivir and other drugs for preparedness to deal with any future requirements, he said.

"As on date there is no shortage of Remdesivir reported by any state and (or) UT," he added.

The Central Drugs Standard Control Organisation (CDSCO) has requested the licensing authorities of all states and UTs through several advisories to instruct their enforcement staff to maintain a strict vigil, especially at sensitive places, on attempts of black-marketing or hoarding of Covid drugs and to take stringent action against the offenders.

Further, the National Pharmaceuticals Pricing Authority under the Department of Pharmaceuticals had directed that "the state governments and UTs may closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding.

"It may also be ensured that there is no violation of the provision of Drug (Prices Control) Order, 2013 (DPCO, 2013) with regard to compliance of ceiling prices/ permissible increase in prices of scheduled/non-scheduled formulations", the minister said.

Source : ETHealthWorld, 04.08.2021

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Discussions yet not over between govt, US-based manufacturers for procuring their COVID-19 vaccines: NK Arora

According to Chief of NTAGI, Dr NK Arora, the country's target of completing COVID-19 vaccination of adults by the end of the year does not take into account the availability of US-based vaccines.

New Delhi: Discussions and negotiations are still not over between the government and US-based COVID-19 vaccine manufacturers for procuring their vaccine, said Dr NK Arora, Chief of National Immunization Technical Advisory Group (NTAGI) on Monday.

"As I understand there are negotiations going on between the government and US-based manufacturers. It is not only Moderna and Pfizer but also Johnson and Johnson involved in the discussion," he said in an exclusive interview with ANI.

It is not certain when these discussions will conclude, he further said.

Dr Arora added that even for donating vaccines to India, the US-based manufacturers have to fulfill paperwork regarding indemnity and liability clauses.

"Even at WHO's COVAX facility, the issue about indemnity and liability clauses has been raised. The US-

based manufacturers have to submit paperwork to donate doses to other countries. Indemnity and liability clauses have to be fulfilled, thus, I am not very certain when that kind of discussion will be over," he noted.

According to him, the country's target of completing COVID-19 vaccination of adults by the end of the year does not take into account the availability of US-based vaccines.

"I must emphasize that in our estimation of vaccine availability, and our capability of vaccinating adults by the end of this year does not take into account any of these vaccines. We are waiting for Zydus Cadila's ZyCoV-D which is the world's first plasmid DNA vaccine and Moderna's mRNA-1273. In fact, Sputnik V and Biological E vaccines have committed to providing 30 crore doses by the end of this year," informed Dr Arora.

Ahmedabad-based Zydus Cadila has submitted data on its three-dose COVID-19 vaccine ZyCoV-D to India's drug regulator Drugs Controller General of India (DCGI) for emergency use authorisation (EUA). However, the decision has been under review by the regulator's Subject Expert Committee (SEC).

"Some more data and analysis have been asked by the expert group and hopefully we should be able to hear back from DCGI's Subject Expert Committee about these issues. However, all of us are very hopeful that this vaccine will be available," he said.

Zydus Cadila had on July 1, requested emergency use approval for ZyCoV-D, its three-dose COVID shot - the world's first plasmid DNA vaccine for human use. If approved it will be the country's second indigenous vaccine after Bharat Biotech's Covaxin.

Source: Shalini Bhardwaj, ANI, 03.08.2021 (ETHealthworld.com)

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Increased risk of heart attack, stroke in first two weeks following Covid: Lancet study

"We found a three-fold increased risk of acute myocardial infarction and stroke in the first two weeks following COVID-19," said Osvaldo Fonseca Rodriguez from Umea University in Sweden, and co-first author of the study.

London: The risk of heart attack and stroke is increased three-fold in the first two weeks following COVID-19, according to a study published in The Lancet journal. The study compared the occurrence of acute myocardial infarction or heart attack, and stroke in 86,742 COVID-19 patients with 348,481 control individuals in Sweden from February 1 to September 14, 2020.

"We found a three-fold increased risk of acute myocardial infarction and stroke in the first two weeks following COVID-19," said Osvaldo Fonseca Rodriguez from Umea University in Sweden, and co-first author of the study.

The risk was same even after the researchers adjusted for known risk factors for acute myocardial infarction and stroke such as comorbidities, age, gender and socio-economic factors.

"The results indicate that acute cardiovascular complications represent an important clinical manifestation of COVID-19," said Ioannis Katsoularis from Umea University, a co-author of the study.

"Our results also show how important it is to vaccinate against COVID-19, in particular the elderly who are at increased risk of acute cardiovascular events," Katsoularis said.

The researchers used two statistical methods in the study: the matched cohort study and the self-controlled case series.

The self-controlled case series study is a method that was originally invented to determine the risk of complications following vaccines, they said.

"Both the methods suggest that COVID-19 is a risk factor for acute myocardial infarction and ischaemic stroke," the authors of the study said.

"This indicates that acute myocardial infarction and ischaemic stroke represent a part of the clinical picture of COVID-19, and highlights the need for vaccination against COVID-19," they said.

In the study, information from national registries from the Public Health Agency of Sweden, Statistics Sweden and the National Board of Health and Welfare were cross-linked for all reported COVID-19 patients.

A control group consisting of four individuals matched to every COVID-19 case on age, gender and county of residence, that had not tested positive for COVID-19. By using historical registry data from the National Board of Health and Welfare's inpatient registry, individuals with a previous myocardial infarction and stroke were identified and excluded from the study.

"It would have been difficult to calculate the risk that COVID-19 contributes to acute myocardial infarction and stroke, if individuals with a prior event were included," said KristerLindmark, a co-author of the study.

"This is because the risk of a recurrent acute myocardial infarction and stroke is increased following a first acute myocardial infarction or stroke," Lindmark added..

Source:PTI , 03.08.2021 (ETHealthworld.com)

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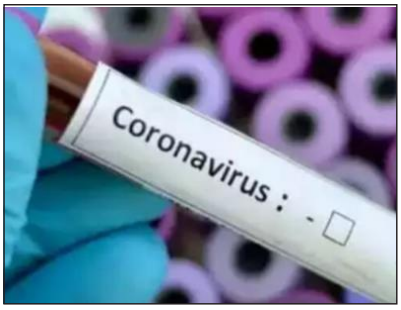
Rajasthan prepares for 3rd wave keeping Delta variant in mind



Out of 655 samples that tested positive for the Delta variant, 305 was in Jaipur, Alwar (107), Udaipur (58), Bikaner (34), Jodhpur (30) and Sikar (29).

JAIPUR: The onslaught of the super-contagious Delta variant during the second wave has prompted the health department to start taking preventive steps in case the third wave hits the state. Out of the 731 samples that tested positive for different variants, 655 were found to be Delta, Alpha (52), Kappa (14), B.1 (10) and one Delta + variant.

Since, Delta had dominated other variants, the health department has started taking preparations keeping in mind the Delta variant.

SAMPLES TESTED POSITIVE IN FOLLOWING...

	Jaipur	Alwar	Udaipur	Bikaner	Jodhpur	Sikar	Rest of Raj	Total
B.1	8	-	1	-	-	-	1	**10**
Alpha	26	3	16	-	1	-	6	**52**
Kappa	6	4	-	-	-	-	4	**14**
Delta	305	107	58	34	30	29	92	**655**
Delta plus	0	-	-	1	-	-	-	**1**
Total	**345**	**114**	**75**	**35**	**31**	**29**	**102**	**731**

"In the second wave, the need for oxygen had gone up as the Delta variant was affecting the lungs and patients were finding it difficult to breathe. In the first wave, we did not face such a situation. In the second wave, the condition of the patients deteriorated much rapidly. Keeping in mind the requirement for oxygen in the second wave, we have done all the preparations for the third wave," said Siddharth Mahajan, secretary (health). Districts such as Jaipur, Alwar, Udaipur, Bikaner, Jodhpur and Sikar, which remained the worst affected due to the second wave, had the highest number Delta variant cases.

Out of 655 samples that tested positive for the Delta variant, 305 was in Jaipur, Alwar (107), Udaipur (58), Bikaner (34), Jodhpur (30) and Sikar (29). The rest of the 92 samples belonged to 27 other districts. Officials said the medicines, which were required in the second wave such as remdesivir and steroids, have also been made available along with eight key tests that were most commonly used in treatment of Covid patients in the second wave.

During the second wave, a lot of patients had developed thromboembolism, cytokine storm, septicemia, myocarditis, systemic inflammatory response syndrome and inflammation, which deteriorated their condition and in some cases even led to death. For diagnosing such conditions, doctors had used tests such as D-dimer, interleukin 6 (IL6), procalcitonin, troponin I and troponin T, ferritin, lactate dehydrogenase (LD or LDH) and c-reactive protein(CRP). Now, as the health department is preparing for the third wave, it is making all the eight tests available in rural areas as well.

Source : TNN, 03.08.2021

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Looking at Covid complications in children, PGI Chandigarh finds hepatitis cases

CHANDIGARH: A study of Covid complications in children revealed that they had hepatitis as well. Multisystem inflammatory syndrome (MISC) was the commonest post-covid presentation in them but this research saw liver disease in those post-covid children who never had such a preexisting case of it. The Post Graduate Institute of Medical Education and Research (PGIMER) did this research together with a medical centre in Madhya Pradesh. The authors, Doctors Sumit Kumar Rawat, Ajit Anand Asati, Ashish Jain, and R K Ratho, have published their work in a preprint. As a retrospective and followup observational study from April

2021 to mid-June 2021, they reviewed all their paediatric patients with acute hepatitis and observed a sudden rise of its features in a group during the second wave of coronavirus infections, where "children or adolescents developed sudden onset of acute hepatitis with no history of pre-existing liver disease in the absence of familiar etiology of acute hepatitis, a recent three-to six-week history of RT-PCR positivity, or a retrospectively proven Covid-19 infection with high titer SARS CoV-2 antibodies". These patients had asymptomatic Covid-19 infection, while another very small group had signs similar to MISC, identified with grave presentation, multiple organ involvement, and Covid-19. Among 33 patients who presented with hepatitis, 25 showed unique features of it associated with hepatitis (CAHC). These patients did not have any typical Covid symptoms.

They had normal to borderline inflammatory markers, and with admission to general care wards, all recovered on supportive treatment without any complications or mortality. However, patients with MISC required admission to critical care. They had high level of inflammatory markers and 3 (37.5%) out of eight had an adverse outcome.

The authors concluded that with emergence of newer variants of concern such as the Delta (which caused a massive wave of Covid-19 in India), CAHC was one of their varied presentations. "This new entity needs to be identified timely and differentiated from other types of hepatitis for appropriate management," the researchers mentioned in the study. The age group of these children ranged from 4 months to 14 years.

Source: Shimona Kanwar, TNN,03.08.2021

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Covid can trigger dormant heart disease to surface in patients

NEW DELHI: Covid-19 can trigger sudden onset of an underlying heart condition, cardiologists from GB Pant Hospital have warned. In a case report published in European Heart Journal, the doctors described how a 57-year-old man with no history of cardiac illness was suddenly rushed to the hospital's emergency block with dangerously high heart rate. "He had received electric shocks twice in a peripheral hospital to stabilise the heart rhythm. We had to administer it again in the emergency ward as the heart rate peaked while he was being wheeled in for tests," said Dr Jama Yusuf, director and professor of cardiology at GB Pant. Later, tests confirmed that the patient was Covid-positive.

Dr Yusuf said tests also revealed raised systemic inflammatory markers and cardiac Troponin-T levels that suggest injury to the heart. Both the markers increased progressively for four weeks during which the 57-year-old remained Covid-positive. They started to decrease and return to the baseline by the sixth week of illness when the patient became Covid-negative.

A team of doctors, led by the head of the cardiology department Dr Saibal Mukhopadhyay, implanted a single-chamber ICD to reduce the risk of sudden cardiac death. ICD is a small battery-powered device that can deliver electric shocks via one or more wires connected to the patient's heart to fix abnormal rhythm.

Though the 57-year-old did not have any history of cardiac illness before, the doctors found out from family members that two of his siblings had died due to sudden cardiac event at ages 55 and 59 years, respectively. "It's possible that the patient also carried the same genetic disorder that caused sudden cardiac death in his siblings. It was lying dormant, completely unknown to the man or his family members, but Covid-19 infection unmasked it by precipitating the heart condition," the cardiologist explained.

The doctor added that the patient was lucky to have reached a super-specialty hospital in time for diagnosis and disease management. "The message for the public from this case study is that Covid-19 doesn't affect the lungs alone. It can cause an array of heart-related complications too. Therefore, it's important to watch out for warning signs, take timely action and rush the patient to a hospital to save their life," Dr Yusuf said.

Source: Durgesh Nandan Jha, TNN , 03.08.2021

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Over 2.75 crore unutilized COVID-19 vaccine doses available with States, UTs

Centre said that 49,85,51,660 vaccine doses have been provided to States and UTs so far, through all sources and a further 20,94,890 doses are in the pipeline.

The Central government on Tuesday informed that more than 2.75 crore unutilized COVID-19 vaccine doses are still available with states, union territories, and private hospitals. "More than 2.75 Cr (2,75,88,573) balance and unutilized COVID vaccine doses are still available with the States/UTs and private hospitals to be administered," said the Ministry of Health and Family Welfare (MoHFW).

The ministry further said that 49.85 crore (49,85,51,660) vaccine doses have been provided to States and UTs so far, through all sources and a further 20,94,890 doses are in the pipeline. Of this, the total consumption including wastages is 47,52,49,554 doses as per data available by the MoHFW.

The new phase of universalization of COVID-19 vaccination commenced from June 21, 2021. The vaccination drive has been ramped up through the availability of more vaccines, advanced visibility of vaccine availability to States and UTs for enabling better planning by them and streamlining the vaccine supply chain.

As part of the nationwide vaccination drive, the Government of India has been supporting the States and UTs by providing them COVID vaccines free of cost. In the new phase of the universalization of the COVID-19 vaccination drive, the Union Government will procure and supply (free of cost) 75 percent of the vaccines being produced by the vaccine manufacturers in the country to States and UTs.

Source : ETHealthWorld, 03.08.2021

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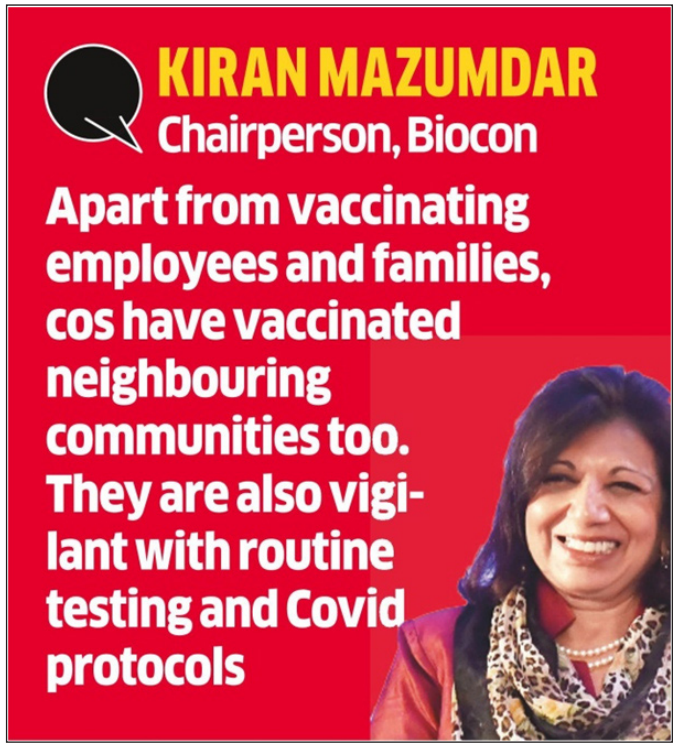
India Inc better prepared for Covid-19 third wave

Officials at the Confederation of Indian Industry (CII) say that with employees vaccinated, companies are more confident this time and are stepping into community vaccinations. Conglomerates are being urged to help ramp up vaccination camps to minimise health risks and lockdowns that will hurt the economy.

India Inc is better prepared to protect businesses and their employees if an expected third Covid wave were to strike, industry captains said, pointing to the multiple de-risking initiatives deployed after the first two viral episodes that took heavy tolls on livelihoods and lives, respectively.

Officials at the Confederation ofIndian Industry (CII) say that with employees vaccinated, companies are more confident this time and are stepping into community vaccinations. Conglomerates are being urged to help ramp up vaccination camps to minimise health risks and lockdowns that will hurt the economy. To be sure, company executives would want no spike in infections at least until September, which is the expected timeline for vaccine supplies to ease.

Harsh Goenka, Chairman, RPG Group, said corporates have de-risked supply chains by ensuring wider sourcing and warehousing avenues. "There is much better preparedness this time around. And yet there are concerns that a third wave might impact children more, which will cause panic," Goenka said. "State governments are also collaborating more with corporations to ensure readiness, building medical infrastructure and oxygen availability.



Statistical models seem to suggest that a third wave could be three to four times more severe than the first wave of 2020, but not as severe as the second one of April 2021, which was eight to ten times more severe than the first wave. CII is relying on the predictions made by the Union Ministry of Science and Technology's mathematical model, SUTRA.

Industry bodies say state governments are also taking an extremely cautious approach, keeping medical infrastructure ready, communicating and collaborating with corporates.

The Maharashtra Chief Minister is understood to have called for a meeting with India Inc heads to discuss preparedness. Naushad Forbes, co-chairman of Forbes Marshall said dealing with the first two waves has given corporates a sense of what to do and work efficiently." There is also greater reliance on the state governments as the restrictions imposed by the specific states were much

more effective the last time, " saidForbes."And as most companies have vaccinated employees and communities, there is a better sense of preparedness this time."

Industry officials say they have vaccinated employees and also enabled community vaccinations for the underprivileged.

We have vaccinated every employee and their families,"saidVenuSrinivasan, chairman, TVS Motor Co.

Corporate officials believe the state of the economy also depends on the health outcomes of Indians and an aggressive vaccination initiative should prevent a damaging third wave. " Industries and businesses have to function normally with Covid-appropriate behaviour and greatly speed up vaccinations. The health of our economy will depend on the health of our people. And governments have to ensure better vaccine availability to ensure that," said the chairman of a leading conglomerate, requesting anonymity.

Bioconchairperson Kiran Mazumdar said besides vaccinating employees and families, companies have vaccinated neighbouring communities too. "There are also vigilant with routine testing and masking and covid protocols, so there is a better state of preparedness, " she said.

BK Goenka chairman, Welspun Group said," In my view, we must calibrate the return to office policy gradually over the next few months and ensuring that employees are vaccinated.

Until then, companies must urge their employees to continue to work remotely as much as possible. India Inc should expedite the vaccination of both doses to the employees since that is in the best interest of all stakeholders".

Source: Kala Vijayraghavan & Lijee Philip, Economic Times, 30.07.2021

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