FREQUENTLY ASKED QUESTIONS (FAQs)
PLI Scheme for Promoting Domestic Manufacturing of Medical Devices as per the Guidelines dated 10.11.2026

Important note on use

This FAQ is intended to facilitate consistent implementation of the revised PLI-MD Guidelines notified on 10-11-2026. It is a guidance document and does not amend, override or create any entitlement beyond the Guidelines, the approval letter or decisions of the competent authorities. In case of any inconsistency, the notified Scheme/Gazette notification, final Guidelines, approval letter and decisions of DoP /Empowered Committee (EC), as applicable, shall prevail.

At a glance: key operational points

Item	Position in the draft Guidelines
Scheme tenure	Up to FY2035-36; maximum 3-year gestation period and maximum 5-year performance period. FY2035-36 is for processing/releasing incentive for the last Performance Year (FY 2034-35).
Target segments	TS1: consumables, disposables and implants; TS2: critical components; TS3: high-end devices in nascent domestic manufacturing; TS4: high-end devices where only assembly operations exist in India.
Minimum investment	TS1/TS3/TS4*: ₹50 crore where average annual turnover in the preceding 3 years is below ₹150 crore; No prescribed minimum investment where average turnover is at least ₹150 crore. TS2: No prescribed minimum investment. *In case of TS4, no requirement of greenfield investment to be prescribed as the incentive would be paid for achieving a higher value chain integration.
Application fee	₹1,00,000 per application, non-refundable; electronic payment.
Bank guarantee	₹30 lakh per application, within 3 weeks of approval; validity 365 days, to be rolled over until at least 50% of committed investment is grounded.
Claims	Maximum two claims per financial year: Q1-Q2 claim within 3

	months after Q2; Q3-Q4 claim within 3 months after the financial year.
Incentive rates on incremental sales over base sales (left to right à form performance year 1 to year 5)	TS1: 7%, 7%, 4%, 3%, 3% TS2: 10%, 10%, 10%, 8%, 6% TS3: 10%, 10%, 10%, 8%, 6% TS4: 7%, 7%, 7%, 5%, 4%
Payment basis	Up to 100% of admissible/allocated amount against verified audited financial statements; 80% against management certificate with 20% retained for annual reconciliation.
PMA processing	PMA to ensure that the received applications are complete in all respects. Also, all claims to be verified by PMA within 45 days (inclusive of all handling queries) before submitting them to DoP for approval.
Quarterly reporting from approved applicants	Self-certified Quarterly Review Report within 30 days after each quarter.

A. Scheme coverage, applicants and eligible products

Q 1. What is the objective and coverage of the Scheme?

A. The Scheme seeks to promote domestic manufacturing of medical devices and development of the ecosystem for finished medical devices and value-chain items. The extended tenure is up to FY 2035-36, with a maximum gestation period of three years and a maximum performance period of five years.

Q 2. What are the four Target Segments?

A. TS1 covers consumables, disposables and implant medical devices; TS2 covers critical components used in manufacturing medical devices; TS3 covers high-end medical devices in a nascent state of domestic manufacturing; and TS4 covers high-end medical devices for which only assembly operations exist in India.

Q 3 . Where can an applicant check whether a product is eligible?

A. The indicative product lists are in Annexure 1A. An item not specifically appearing in the indicative list may still be considered, but its approval rests with the EC. Applicants should identify the precise product, its HSN code and the relevant Target Segment in the application.

Q 4. Can a product/component be applied for under more than one Target Segment?

A. No. Where a component/device appears in more than one Target Segment because of potential applications across segments, the applicant may apply for it under only one Target Segment. Where a broad product category is listed in one segment but a specific product is separately listed in another, the specific product is to be applied for under the segment in which it is specifically listed.

Q 5. Can an applicant apply for more than one product or Target Segment?

A. An applicant may submit any number of applications in each Target Segment. A separate application is required for each Target Segment, and the applicable eligibility conditions must be met separately for each segment.

Q 6. Who can apply?

A. A company or Limited Liability Partnership registered in India, having positive net worth (including the position of group companies as specified in the Guidelines), may apply, subject to the other eligibility conditions. The applicant should not have been declared bankrupt, a wilful defaulter/defaulter, or reported as fraud by a bank, financial institution or NBFC.

Q 7. Does the project have to be greenfield?

A. A greenfield project is required for TS1, TS2 and TS3, except that TS4 is specifically exempted from the greenfield requirement. TS4 focuses on deepening value-chain integration in existing high-end device assembly operations. The project may be at one or more locations in India. In case of TS 2, exemption has been given for minimum investment requirement (₹ 50 Cr for entities with turnover less than ₹ 150 Cr). However, greenfield investment is still required.

Q 8. What qualifies as a greenfield project?

A. It means a new production facility or a new plant/additional production lines within the premises of an existing production facility. Where a new plant/ additional production lines is established within existing premises, separate records must be maintained for the new plant/ additional production lines for Scheme purposes. Existing ancillary utilities may be used, but the historical investment in those utilities cannot be counted as committed investment under the Scheme.

Q 9. Can the applicant change the project location or approved product?

A. A change in the greenfield project site requires DoP approval. An applicant may change approved products mid-course from the indicative list within the

relevant Target Segment, but DoP approval is required.

Q 10. Does approval under this Scheme affect eligibility under another Government scheme?

A. No. The Guidelines state that eligibility under this Scheme does not affect eligibility under any other scheme, and vice versa.

Q 11. Whether an applicant can apply in multiple target segments with the same investment?

A. Yes. An applicant can apply in multiple target segments, but such applicant shall need to make fresh investment in each of the target segments as per the eligibility conditions of applicable turnover requirements viz a greenfield plant (except in TS4) shall have to be set up for each application.

B. Investment, project readiness and eligibility thresholds

Q 12. What is the minimum investment requirement?

A. For TS1, TS3 and TS4, an applicant whose average annual turnover in the last three years is below ₹150 crore(in Medical device manufacturing) is required to make a minimum investment of ₹50 crore. Where the average annual turnover is ₹150 crore or more, no minimum investment threshold is prescribed. TS2 has no minimum investment condition. For TS4, the ₹50 crore requirement, where applicable, is for achieving substantial value-chain integration; a new greenfield facility is not required.

Q 13. What expenditure can be counted as investment?

A. Eligible heads include expenditure on new plant, machinery and equipment; associated utilities; tools, dies, moulds, jigs and fixtures; eligible manufacturing-related IT/ITES infrastructure; qualifying R&D and product development; and qualifying transfer-of-technology expenditure from an unrelated entity. Non-creditable taxes and duties are included as specified in the Guidelines.

Q 14. Is expenditure on land or factory building eligible?

A. No. Expenditure on land and building, including factory building/construction, is expressly excluded from investment for determining eligibility.

Q 15. Can raw material or consumables be counted as investment?

A. No. Consumables and raw materials used for manufacturing are not treated as investment.

Q 16. From what date is investment counted?

A. The investment cut-off date stated in the Guidelines is 1 April 2026. The date of the purchase invoice is treated as the date of investment. Investment must

also satisfy the applicable scheme-notification and capitalization requirements in the Guidelines.

Q 17. Must the investment be capitalised in the applicant's books?

A. The relevant investment heads are required to be capitalised in the applicant's books of account, as certified by the Statutory Auditor. The specific provision for clinical-trial expenditure allows it to be counted subject to the stated cap, irrespective of whether it is capitalised.

Q 18. Can leased machinery qualify?

A. Yes, if purchased/leased in the name of the applicant and, where leased, the lease is in the nature of a financial lease under the applicable accounting standard (AS 19 or Ind-AS 116). Legally valid procurement/lease documents and applicable tax/duty compliance are required.

Q 19. Can machinery or tools be located outside the applicant's premises?

A. Tools, dies, moulds, jigs, fixtures and related parts/accessories/spares may be located outside the applicant's premises, subject to appropriate undertakings from the custodian and valid legal agreements. They must not be located outside India.

Q 20. Are R&D expenses eligible?

A. Qualifying capital expenditure on R&D and product development related to the Target Segments may be counted. The definition includes relevant test and measuring instruments, prototypes, design tools, directly used R&D software/licences, technology, IPRs, patents and copyrights, subject to the documentation and accounting requirements.

Q 21. Are clinical-trial expenses eligible?

A. Costs incurred by the applicant for clinical trials in India of an eligible product may be counted, subject to a cap of 10% of the approved applicant's committed investment. Where doubt arises regarding correctness or reasonableness, a two-member committee nominated by DCGI examines the claim and recommends the admissible amount to DoP.

Q 22. Does technology transfer from a parent or group company count towards meeting the minimum investment threshold?

A. No. A transfer-of-technology arrangement with a parent company or group company is excluded. Technology transfer from an unrelated entity may qualify, subject to the required Statutory Auditor certificate and other supporting documents.

Q 23. How is investment verified?

A. The applicant is required to provide a certificate from a PMA/DoP-empanelled Chartered Engineer after physical inspection of the plant. The PMA/DoP may also rely on the specified valuation/cost reasonableness certificates and supporting records. The PMA/DoP may conduct site visits and seek additional information.

Q 24. What happens if committed investment or another annual eligibility condition is not met in a particular year?

A. The applicant is not eligible for incentive for that particular year if the applicable committed-investment, self-declared value-chain integration or sales-growth CAGR condition is not met. This does not automatically bar claims for later years, provided the conditions for those later years are met. Carry-forward is subject to the applicable Scheme provisions.

Q. **25.** If an applicant company has an average annual turnover of ₹150 crore or more from business activities other than the sale of manufactured medical devices, will such turnover be considered for determining the minimum investment requirement under the Scheme?

A. No. For the purpose of determining the minimum investment requirement under Para 4.2.2.1 of the Guidelines, only the applicant's average annual turnover arising from the sale of self-manufactured medical devices shall be considered. Turnover from other business activities, including trading, services or sale of products other than manufactured medical devices, shall not be included. Where the applicant's average annual turnover from the sale of manufactured medical devices during the preceding three financial years is less than ₹150 crore, the minimum investment requirement of ₹50 crore shall apply under TS1, TS3 and TS4, irrespective of the applicant's total turnover from other business activities.

Q. 26. Will software development or services involved in the manufacturing of an approved PLI product/component be included while calculating value chain integration?

A. No. The value chain integration will be calculated strictly on the basis of the Bill of Materials (BoM) considering only physical components.

Q. 27. Whether the investment requirement under the scheme needs to be met separately for each approved product or can it be met by combining investments across all approved products?

A. The investment requirement is not required to be met separately for each

approved product in a single application. The investment made by the applicant across all approved products within a particular Target Segment may be aggregated for determining compliance with the applicable investment threshold. However, the eligibility criteria, including the investment threshold, are required to be met separately for each Target Segment, wherever applicable, in accordance with Para 6.2 of the Guidelines. Accordingly, investments cannot be pooled across different Target Segments to meet the investment threshold of a particular Target Segment.

C. Application, scrutiny and approval process

Q 28. How to submit an application under the scheme?

A. The application under the Scheme shall be submitted through online mode only on following link:

https://pli-medicaldevices2.pharma-dept.gov.in/

Before submitting an application, the registration of the applicant on the PLI portal is mandatory

Q 29. What is the application fee?

A. The fee is ₹1,00,000 for each application, is non-refundable and is payable electronically. A separate application for another Target Segment attracts a separate application fee.

Q 30. What documents and information should applicants prepare?

A. Applicants should prepare, among other items: incorporation certificate; audited financial statements; PAN and GST details; Memorandum and Articles of Association; authorization for the signatory; shareholding details where applicable; financial/credit-history information; Statutory Auditor and Company Secretary/Board certificates; product and Target Segment details; sales baseline; committed investment; year-wise investment and sales projections; value-chain integration plan; employment projections; regulatory/environmental clearances and timelines; and proof of fee payment. The detailed list and formats in Annexure 4 should be followed.

Q 31. What does the PMA check at the preliminary stage?

A. Annexure 6 lists the preliminary checks: application fee, net worth, whether the proposed products fall within the Target Segments, eligibility for the proposed segment, proposed investment wherever applicable, year-wise sales CAGR wherever applicable, committed value-chain integration and prima facie completeness.

Q 32. How long does preliminary scrutiny take?

A. The PMA is to complete prima facie examination within 15 working days of receipt of the original application or revised application. If incomplete, PMA is to inform the applicant within that period. The applicant is required to complete the application within 15 working days of that communication, failing which the application is closed.

Q 33. Does an acknowledgement mean that the applicant is approved?

A. No. Acknowledgement confirms only that the application has passed the stated prima facie threshold scrutiny. It is not approval and does not by itself confer eligibility to claim incentives.

Q 34. When are applications processed?

A. Applications received by the last day of each month during the application window are taken up for processing. The application window shall remain open over an extended period of time.

Q 35. Who evaluates and approves applications?

A. The PMA examines applications and makes recommendations. The PEC examines/evaluates proposals, which are thereafter submitted to DoP for approval.

Q 36. What is the approval timeline?

A. The applications will be processed within 60 days from the last day of the month, when the received applications shall be harvested. Following final approval, the PMA/DoP is to issue the approval letter within five working days.

Q 37. What will the approval letter specify?

A. It will specify the applicant, Target Segment, eligible products, proposed committed investment, base year/base sales (where applicable), scheduled commercial-production commencement, sales CAGR, current and projected value-chain integration status, and any additional conditions imposed by the DoP.

Q 38. Does the approval letter guarantee payment of incentive?

A. No. Approval is not a guarantee of incentive disbursement. Payment depends on verification of claims and meeting all other requirements/ commitments as enshrined in the approval letter.

Q 39. What bank guarantee is required after approval?

A. Within three weeks of the approval letter, the selected applicant must furnish a bank guarantee of ₹30 lakh per application, along with the prescribed undertaking. It must be issued by a scheduled commercial bank, remain valid for

365 days and be rolled over until at least 50% of committed investment is grounded.

Q 40. When is the bank guarantee released or invoked?

A. The bank guarantee is released when at least 50% of committed investment is achieved within three years from approval. If the applicant fails to ground at least 50% of committed investment even after three years from approval, the guarantee is liable to be invoked. The applicant must maintain/roll over the guarantee as required.

Q 41. What happens if the applicant becomes ineligible or declines approval?

A. If the applicant is found ineligible, fails to comply with the Scheme requirements or declines the approval offer, the envisaged incentive claim may be forfeited, the approval offer cancelled and the bank guarantee invoked if it has not already been released. The offer may then be extended to a waitlisted applicant for the remaining period.

D. Base year, sales growth and incentive calculation

Q 42. How is the base year determined for an existing manufacturer?

A. For a product already manufactured by the applicant or its group companies, the base year is the year in which the highest sales of that product were achieved in the three financial years preceding the application. Base sales are the highest annual domestic-plus-export sales in those three years.

Q 43. What is the base sales treatment for a new manufacturer or a product with no past sales?

A. Where the applicant and its group companies are not engaged in manufacturing the product, base sales are zero. The Guidelines state that the prescribed sales CAGR is to be achieved over the first-year sales. Annexure 3 contains specific treatment for new entities/new products under TS1.

Q 44. What is the basic incentive formula?

A. Incentive = Net Incremental Sales of eligible product(s) × applicable incentive rate. Eligible product(s) are the ones mentioned in the approval letter, and generated at the approved manufacturing facility.

Q 45. What is included in eligible net sales?

A. Eligible sales exclude GST and other indirect taxes, discounts, rebates, credit notes, sales returns, trading/resale value, installation, maintenance, warranty, financing and non-manufactured services/content. For bundled systems, the value attributable to the eligible manufactured product must be allocated

consistently, excluding the specified service and non-product elements.

Q 46. How are sales returns treated?

A. Sales returns reduce gross sales turnover. If the original sale was already included in an earlier claim, the return is adjusted against gross sales turnover in the period in which the return actually occurs.

Q 47. How is in-house consumption of an eligible product treated?

A. For an eligible product consumed in-house by the applicant, the net sales value is the actual cost of production certified by a statutory auditor.

Q 48. Can the applicant claim incentive on components it manufactures and uses in its own finished device?

A. No separate incentive is payable on components manufactured by the applicant and consumed internally in manufacturing finished medical devices. Incentive on such components is admissible only for sales to third parties.

Q 49. Are exports included?

A. The base-sales definition includes domestic and export sales. The claim form and quarterly review format separately capture domestic sales and exports. For TS1, Annexure 3 also specifies an SRA-country regulatory approval and sales requirement in such countries.

Q 50. What are the rates and sales thresholds by Target Segment?

A. Annexure 3 provides tapering incentive rates and segment-specific conditions. TS1: 7%, 7%, 4%, 3% and 3% over performance years 1–5; sales growth of 10% CAGR is required, with the SRA approval-and-sales condition stated in Annexure 3. TS2: incentive rates are 10%, 10%, 10%, 8% and 6% from 1 to 5 years; sales growth requirements are 2%, 3%, 4% and 5% in years 2–5 over year-1 sales, and Annexure 3 separately describes a 7%, 7%, 7%, 5%, 3% base rate plus an additional 3% upon achievement of committed value-chain integration. TS3: headline rates are 10%, 10%, 10%, 8% and 6%; no sales CAGR is required, but committed value-chain integration is mandatory, with Annexure 3 separately describing 7%, 7%, 7%, 5%, 3% plus an additional 3% on fulfilment of value chain integration commitment. TS4: 7%, 7%, 7%, 5% and 4%; no minimum sales threshold or sales CAGR, but committed value chain integration is mandatory.

Q 51. What is the SRA requirement under TS1?

A. The draft requires regulatory approval from a Stringent Regulatory Authority country (USA, EU, Canada, Japan, Australia, Switzerland or UK) and sales in such country/countries in any quantity. The Guidelines should be read with the

applicable product-specific regulatory requirements.

Q 52. How is value-chain integration measured?

A. The claim documentation describes value-chain integration on a Bill of Materials (BoM) basis. Percentage of value addition = (Domestic Bill of Material ÷ Total Bill of Material) × 100. The detailed definitions of domestic BoM and total BoM in Annexure 10 should be applied. It is only on input materials and excludes services, product support etc.

Q 53. Can a shortfall in sales growth be made up later?

A. For TS 1 and TS 2, scheme guidelines permit a shortfall in the minimum sales-growth requirement in a particular performance year to be made up in the subsequent performance year without making the applicant ineligible for the year in which the shortfall occurred. In case the applicant in TS 1 is able to achieve CAGR of 8% in a particular year & 14% in the next year, then it can claim incentive for both the years in the 2nd year.

E. Claims, verification, disbursement and reconciliation

Q 54. How many claims can an applicant file in a financial year?

A. A maximum of two claims: (i) the first claim for eligible sales during Q1 and Q2, to be filed within three months from the end of Q2; and (ii) the second claim for eligible sales during Q3 and Q4, to be filed within three months from the end of the financial year. An approved applicant shall submit its claim through the designated online portal.

Q 55. Can the same sales be included in both claims?

A. No. The two claims must cover distinct periods and no sale may be claimed more than once.

Q 56. Can a claim be revised or supplemented after filing?

A. A claim, once submitted, cannot be revised or supplemented through another claim. However, a rectified claim for an amount disallowed by the PMA may be submitted within 30 days of communication of the disallowance.

Q 57. What form is used for an incentive claim?

A. The applicant must use the claim form in Annexure 10 and submit the prescribed supporting documents. The PMA may seek additional information or documents for verification.

Q 58. What key information does the claim form require?

A. The claim form captures applicant and approval details; Target Segment and

eligible products; claim period; cumulative investment and employment; domestic and export revenue split between manufacturing, trading and services; eligible-product sales quantities; import details; exports to SRA countries; and certificates/undertakings relating to product conformity, statutory clearances, investment, sales growth, value-chain integration and installation/use of plant and machinery.

Q 59. What is the difference between the 100% and 80:20 payment routes?

A. Where audited financial statements supporting the claim are furnished and verified, 100% of the approved admissible incentive may be released. Where management certificate and other prescribed documents are submitted, 80% of the approved admissible incentive may be released and 20% retained till the time audited balance sheet is available. Both routes remain subject to fund availability and pro-rata allocation.

Q 60. Is the 80:20 split applied before or after pro-rata allocation?

A. After pro-rata allocation. The 80:20 split applies to the admissible amount actually allocated to the applicant, not to the gross amount claimed or the amount that would have been admissible absent the fund limitation.

Q 61. When must the annual audited reconciliation be submitted for an 80% payment?

A. The applicant must submit annual audited financial statements and reconciled statements of sales and eligible investments, with supporting records, by 15 October following the end of the relevant financial year.

Q 62. When is the retained 20% released?

A. The PMA verifies the annual audited/reconciled documents and then DoP shall release the retained 20% relating to both claims of the preceding financial year within 30 days of receipt of complete documents. If documents are not submitted by 15 October, the retained amount remains withheld until submission and verification.

Q 63. What if the annual reconciliation reveals excess payment?

A. Any excess is first adjusted against the retained amount. Any remaining excess is recoverable under the Guidelines, with interest at the three-year SBI MCLR prevailing on the date of disbursement, compounded annually from disbursement until refund.

Q 64. Does an applicant receiving 100% against audited statements need to submit the annual reconciliation again?

A. No separate annual submission under the relevant reconciliation provision is

required for an applicant that received 100% on the basis of audited financial statements. However, DoP may seek annual audited/certified statements and other records for verification or audit whenever required.

Q 65. How long does PMA take to examine a complete claim?

A. The PMA is to examine claims, verify eligibility/admissibility and submit recommendations to DoP within 45 days of receipt of a complete claim. The 45-day period is linked to receipt of a complete claim; the PMA may seek further documents/information, but shall have to close the claims within the prescribed the 45 days.

Q 66. Who takes the final decision on a claim?

A. The DoP may approve, modify or reject claims. Reasons for modification or rejection are to be recorded in writing.

Q 67. How is the incentive paid?

A. After approval and completion of prescribed formalities, DoP disburses the incentive directly into the applicant's bank account through PFMS or another approved mechanism.

Q 68. Is there a ceiling on the incentive that one applicant or group can claim?

A. The Guidelines state that there is no annual or overall ceiling on the amount claimable by an applicant or its group companies. Actual disbursement remains subject to eligibility, the annual incentive outlay, half-yearly sub-buckets and pro-rata allocation.

Q 69. How are half-yearly funds allocated and shortages managed?

A. The remaining outlay of approximately ₹2,700 crore is distributed across seven annual buckets for Scheme years 2 to year 8: ₹150 crore, ₹250 crore, ₹500 crore, ₹600 crore, ₹700 crore, ₹300 crore and ₹200 crore, respectively. Each annual bucket is divided into two equal sub-buckets corresponding to Q1-Q2 and Q3-Q4. Unutilised funds move to the subsequent half-year. If claims exceed available funds, disbursement is pro-rata and the unpaid amount is an outstanding shortfall. Surplus after meeting current half-year claims is first applied to previous half-year shortfalls pro-rata; remaining balance is carried forward. Year-end balances/shortfalls move to subsequent Scheme years, subject to the overall outlay.

Q 70. What records can the PMA verify?

A. The PMA may verify supporting documents, sales realisation, bank statements, investment records, auditor certificates and physical progress of the

approved project. It may inspect manufacturing units/offices and seek additional information. Material deviations or non-compliance are to be reported to DoP.

Q 71. After approval of an existing product under the Scheme, will incentives be provided on sales from both the existing capacity and the additional capacity created?

A. No. In the case of existing manufacturers, the incentive shall be admissible only on sales generated from the additional/new production capacity created for the approved product under the Scheme. The eligible sales cannot exceed the additional production capacity created. Sales from the existing production capacity shall not be eligible for incentives. For determining incremental sales, the base sales of the product shall be considered.

Exception: The above restriction regarding additional/new production capacity shall not apply to TS4. Incentives under TS4 shall be governed by the applicable provisions relating to incremental sales and achievement of the prescribed value chain integration requirements.

Q72. Whether an approved applicant is required to furnish an audited breakup of sales and imports relating to non-approved products and other business activities, as prescribed under Annexure 10, while submitting an incentive claim?

A. No. For the purpose of determining the incentive payable under the Scheme, the Statutory Auditor's certification shall primarily cover the sales turnover and quantity of approved/eligible products, along with other parameters specifically required for determining eligibility and incentive admissibility. The applicant shall, however, disclose its total revenue from operations, including revenue from other manufacturing activities, trading and services, for reconciliation with its audited financial statements. Such disclosures, insofar as they relate to non-approved products and other business activities, may be furnished on a self-certified basis and need not be separately certified by the Statutory Auditor. The DoP/PMA may seek additional information, supporting documents or a detailed breakup of such sales and imports wherever considered necessary for verification of the claim.

F. Monitoring, integrity, changes and consequences

Q 73. What quarterly reporting is required after approval?

A. Each approved applicant must submit a self-certified Quarterly Review Report in Annexure 8 within 30 days from the end of each quarter.

Q 74. Is the applicant required to provide consent for audit and permit inspection of its manufacturing facilities and offices under the Scheme?

A. Yes. The application includes an undertaking consenting to audit of the manufacturing site/offices. The applicant and relevant agencies/consultants must permit the PMA or authority designated by DoP to verify the facility and documents submitted for approval and incentive claims.

Q 75. What integrity undertakings are required?

A. Annexure 11 contains Format-A and Format-B. Format-A is to be submitted by applicants whose applications or claims are under consideration; applications/claims without it are not processed. Format-B confirms continuing integrity compliance after claim submission and before release of funds; incentive release is withheld until it is furnished. Both are to be signed by the full-time Director/CEO/MD with designation and authorization.

Q 76. What if the applicant's shareholding changes?

A. The applicant must inform the PMA/DoP of any change in shareholding after updating records with the Registrar of Companies. A change resulting in a successor-in-interest must be referred through the PMA for EC approval for consideration of incentive disbursement. Investment already undertaken by the original approved applicant may be considered, subject to EC approval and conditions.

Q 77. Are related-party transactions subject to special treatment?

A. Yes. Related-party transactions are addressed in the residual provisions of the Guidelines and are subject to the applicable accounting-standard definition and Scheme conditions. Applicants should maintain transparent, auditable documentation and seek PMA/DoP clarification where treatment is uncertain.

Q 78. What are the consequences of excess claims or misrepresentation?

A. Excess incentive must be refunded with interest at the three-year SBI MCLR prevailing on the date of disbursement, compounded annually. Where eligibility or incentive has been obtained through misrepresentation or falsification, DoP may require refund with interest after giving the applicant an opportunity of being heard. Other legal remedies may also be available under the prescribed undertakings.

Q 79. Can the EC grant an extension or modify conditions?

A. The EC may grant an extension for project commissioning, review bucket sizes, approve changes to eligible products within the stated framework, and amend the Scheme/Guidelines. In force majeure cases, it may amend, modify or

withdraw a clause. Applicants should not assume an extension or waiver unless approved by the competent authority.

Q 80. Where should an applicant seek clarification?

A. The applicant should first raise the issue with the PMA, which may refer matters requiring clarification to DoP. The Guidelines state that DoP's decision on matters referred for clarification shall be final.

G. Illustrative operational examples

Example 1 – Claim deadline

For a financial year ending 31 March, the Q1-Q2 claim is due within three months after 30 September; the Q3-Q4 claim is due within three months after 31 March. Applicants should follow the exact date and submission mechanism.

Example 2 – 80:20 payment after pro-rata allocation

If an applicant's admissible claim is ₹10 crore but the half-yearly pro-rata allocation provides ₹6 crore, the 80:20 route is calculated on ₹6 crore: ₹4.8 crore may be released initially and ₹1.2 crore retained, subject to verification and the other conditions. Prorata fund allocation is based on the annual bucket size prescribed in the schedule guidelines.

Example 3 – Internal consumption of components

If a company manufactures a component and uses it in its own finished medical device, it cannot claim a separate incentive on that component's internal consumption. The component incentive is admissible only for sales to third parties.

Example 4 – Investment threshold

If the applicant's average annual turnover for the last three years is ₹120 crore and it applies under TS1, TS3 or TS4, the ₹50 crore minimum investment condition applies. If the average turnover is ₹160 crore, no minimum investment is prescribed for those segments. TS2 has no minimum investment requirement even for entities whose annual turnover is less than ₹150 crore.

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