

Frequently Asked Questions

Government of India Ministry of Chemicals and Fertilizers Department of Pharmaceuticals

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Frequently Asked Questions

This document provides answers to Frequently asked questions (FAQs) regarding the Promotion of Research and Innovation in Pharma MedTech (PRIP) Scheme. This document will be updated periodically based on additional queries received, ensuring all interested entities have access to relevant information.

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Scheme Overview

1. What is the PRIP Scheme?

The PRIP (Promotion of Research and Innovation in Pharma MedTech Sector) scheme, launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, is aimed at strengthening research and innovation in the Pharmaceutical and MedTech sectors. The objectives of the scheme include:

- 1. Enable rapid discovery, development and commercialization of drugs.
- 2. Enable innovation in medical devices.
- 3. Promote industry academia collaboration.
- 4. Transform these sectors from cost-based to innovation-based.

2. What is the currently approved timeline of the scheme?

The scheme is currently approved to run for 5 years, from FY 2023-24 to FY 2027-28

3. What is Component A of the Scheme?

Component A focuses on establishing Centers of Excellence (CoEs) at the existing National Institutes of Pharmaceutical Education & Research (NIPERs) in seven locations. These CoEs will specialize in specific areas of Pharma and MedTech R&D

4. What is Component B of the Scheme?

The financial assistance under this component would be provided to promote R&D in six priority areas. The component is further divided into three different categories: B-I, B-II and B-III.

5. What are the 'Priority Areas' under component B?

Priority areas are themes within the Pharma & MedTech R&D from which the projects for funding under PRIP scheme will be invited. There are 6 priority areas identified under the component B of the PRIP Scheme, namely:

- 1. New Chemical Entities, New Biological Entities and Phyto-Pharmaceuticals
- 2. Complex Generics and Biosimilars
- 3. Precision medicine
- 4. Medical Devices
- 5. Orphan Drugs
- 6. Drug development for antimicrobial resistance (AMR)

Scheme Priority areas

6. Is funding under the PRIP scheme limited to the sub-areas under each priority area as defined in the operational guidelines?

No, the sub-areas defined for each priority area in scheme operational guidelines are "illustrative" and not exhaustive.

7. Does the discovery phases of drugs for AMR also covered under funding?

Yes, as per the applicable project category B I/B II/B III the discovery and development phases of the R&D value chain of the drugs for AMR will be covered

8. Which all diseases are covered under PRIP scheme for Orphan drugs?

About 450 rare diseases recorded in India (in tertiary care hospitals) are covered under scheme priority area 5, Orphan drugs.

9. Does the PRIP scheme fund projects for animal health (veterinary), or only human healthcare?

PRIP currently supports innovations targeted for human use only. Projects focused on veterinary, or animal health are not covered. In other words, to be eligible, your project should ultimately be aimed at pharmaceutical or medical technology applications benefiting human healthcare.

Eligibility criteria under component B

10. Who can apply for funding under component B?

Eligible applicants include pharmaceutical or MedTech companies (Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP), or a Company /Group of companies), MSMEs (as per the definition in THE GAZETTE OF INDIA notification, Ministry of micro, small and medium enterprises dated 1st June 2020), or startups registered in India. Eligibility is determined on a range of factors including based on the annual turnover of the company and the Technology Readiness Level (TRL) of the project.

11.Are foreign or multinational companies eligible to apply under PRIP?

Yes. The PRIP scheme supports projects from both Indian companies *and subsidiaries of multinational (MNC) companies*. An Indian-incorporated entity that is wholly or partly foreign-owned is eligible to apply, as long as it meets the scheme's other criteria. (In Category B I, such companies would still need a collaboration with an Indian government research institute.)

12. Are section 8 companies eligible to apply under PRIP?

No. The applying entity should be either of the following types - Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP), or a Company /Group of companies

13.Can two or more eligible entities jointly apply for funding under PRIP scheme?

No, entities cannot jointly apply under PRIP scheme. However, for joint entity projects one of the partnering entities can apply under PRIP scheme

14.Can I apply as an individual or unregistered startup, and incorporate later if selected?

No – PRIP funding can only be awarded to a **registered entity**. The scheme is "industry-facing," so you must have a company or startup officially registered in India to apply. You cannot apply as an individual researcher or an unincorporated team and then form a company later. If you intend to apply under **Category B III**, ensure your startup is registered (and obtain a DPIIT startup recognition or Udyam MSME certificate as applicable) *before* submitting your application.

15.What are the eligibility criteria under Component B?

B-I

Applicants must be established pharmaceutical or MedTech companies with:

- 1. Annual revenue $\geq \gtrless 1,000$ Cr (Pharma) or $\geq \gtrless 250$ Cr (MedTech)
- 2. R&D expenditure of 3-5% (Pharma) or 1-3% (MedTech) of total revenue in the last five years
- 3. Collaboration with a Government research institution (Refer Operational Guidelines)
- 4. Projects in priority areas at any TRL 1 to 9

B-II: Entities working on R&D projects in priority areas that are at TRL 5 or 6

B-III: Startups and MSMEs working in priority areas at TRL 1 onwards to TRL 4

16.Are there any revenue or R&D spend requirements for applications in the BII or B III category?

No, there are no minimum revenue or R&D spend requirements for applications in B II or B III category. However, the company should be able to demonstrate R&D focus and availability of co-funding as applicable.

17.I have a project in TRL 4 stage. As an MSME or startup which category should I apply under PRIP scheme?

Startups/MSMEs can apply under Category B-II or B-III of PRIP. B-II supports TRL 5–9, while B-III supports TRL 1–4. Choose the category based on your current TRL and the progress you expect within the scheme duration. If you aim to reach beyond TRL 5 during the project, B-II is recommended. Otherwise, opt for B-III to complete the journey up to TRL4

18.Can the projects currently or in past funded by any other government scheme apply for PRIP funding?

Yes, PRIP scheme allows any project currently or in the past funded by any of the government scheme to apply for PRIP funding subject to the condition that funds made available under the scheme is for augmentation and there are no duplication in expenditures booked under the two scheme.

19.Is there a limit on the number of the projects an entity can apply?

There is no limit on the number of projects that an entity can submit.

20.What is the maximum number of projects that entity can get funding for under PRIP scheme?

A maximum of 3 projects per entity will be funded under the PRIP scheme

21.Can the same project be submitted to multiple categories?

Yes, Pharma & MedTech companies may submit projects in TRL (5-9) under B I and B II both, but the funding will be granted under either one of the categories.

22.If my project is India-originated but targets foreign markets only, is it still eligible?

No, PRIP funding will support projects which include India as one of the target markets for product/ technology commercialization

Industry Academia partnership for category B

23. Who can be an academic partner under B-I category?

Applicants can partner with any institute of national importance. An illustrative non-exhaustive list of institutions provided in the scheme's operational guidelines – Appendix X.

24.Can the academic partner be a private institute?

No. As per current guidelines, the academic partner must be a government institute of national repute.

25.Can academic institutions apply for funding under B I category?

No, academic institutions cannot apply for funding under B I category. Academic institutions can partner with Pharma or MedTech companies which meet the company eligibility under B I category. However, the company will have to be the applicant under PRIP scheme.

26.Can companies applying under B II and B III categories also have academic partnerships?

Yes, the scheme does not prohibit any applying entity to have an academic partner. However, it is an eligibility requirement under only B I category

27.What will be the IP rights ownership construct between academic partner and companies?

Under B-I category, decision regarding IP rights, ownership of the assets created would be as per prior agreement between the company and the individual institute.

Funding under component B

28. How much funding will be provided under Component B?

Funding varies by category:

- 1. Category B-I: 35% of total project cost or ₹125 Cr (whichever is less)
- 2. Category B-II: 35% of total project cost or ₹100 Cr (whichever is less)
- 3. Category B-III: Up to ₹1 Cr per project

29. Will the funding obtained from any other government scheme be considered acceptable source of co-funding under PRIP scheme?

Yes, any funding obtained from any other government scheme will be considered acceptable source of co-funding under PRIP scheme subject to the condition that funds made available under the scheme is for augmentation and there is no duplication in expenditures booked under the two scheme.

30.Will the funding obtained from any institutional investors (Venture capital, private equity, strategic investors) be considered acceptable source of co-funding under PRIP scheme?

Yes, any funding obtained from any private institutional investors (venture capital, private equity, strategic investors) will be considered as acceptable source of co-funding under PRIP scheme

31.Will the funding obtained from internal budget allocation be considered acceptable source of co-funding under PRIP scheme?

Yes, any funding obtained from internal budget allocation will be considered as an acceptable source of co-funding under PRIP scheme

32.Will the funding obtained from individual investors be considered acceptable source of co-funding under PRIP scheme?

Yes, any funding obtained from individual investors will be considered acceptable source of cofunding under PRIP scheme

33. Will the funding obtained from friends, family and social network be considered acceptable source of co-funding under PRIP scheme?

Yes, any funding obtained from friends, family and social network will be considered acceptable source of co-funding under PRIP scheme. Suitable documents may be provided for the same.

34. Will self-funding be considered acceptable source of co-funding under PRIP scheme?

Yes, self-funding will be considered acceptable source of co-funding under PRIP scheme. Suitable documents may be provided for the same.

35.Is foreign funding (grants/investments) considered valid co-funding under PRIP?

Yes, foreign funding (grants/investments) will be considered acceptable source of co-funding under PRIP scheme

36.How can the funding be used?

The funding will include expenditure incurred on manpower specifically hired for the projects, raw products, equipment, consumables, cost of clinical trials regulatory process, contingencies etc.

Under category B-I the investment made by the companies on the projects at the institute would be supported by funding.

37.Can the funding be used to cover the cost of global trials?

This feedback is noted and may be considered subject to approval of competent authority - the funding may be used to cover the cost of global trials contingent up on trial being done in India as well. The same needs to be included and approved into the business case / project budget at the time of funding.

38.Can the funding be used to avail services of any foreign entity required during the R&D journey?

The funding can be used to avail services of any foreign entity required during the R&D journey. The same needs to be included and approved into the business case / project budget at the time of funding.

39.Can the funding be used to in-license a technology for further development?

A share of funding received under PRIP scheme can be used towards in licensing a technology from any Indian institutes under central government. However, the project will need to develop the in-licensed technology further with the goal of commercializing it.

40.Can PRIP funds be used to buy equipment or build infrastructure?

Yes. The PRIP scheme allows funding to be used for capital expenditures like equipment purchase or research infrastructure, if they are necessary for the project. There is a provision to spend a portion of the fund on equipment and lab infrastructure under the project.

41.Does PRIP support costs already incurred, or only future expenses?

PRIP funding will cover future R&D activities – it is not meant to reimburse past expenses. The scheme will fund the work that takes place from your project stage (at time of funding) onward.

42. How will the funds be disbursed?

Funds will be released as per milestones:

- 1. 1st Installment: 10% at agreement signing.
- 2. 2nd Installment: 30% after 1st milestone completion
- 3. 3rd Installment: 30% after 2nd milestone completion
- 4. Final Installment: 30% on project completion

43. How are the project milestones defined?

The Technical Committee will define the milestones for the selected project as per current operational guidelines. An updated guideline will be shared on the PRIP scheme webpage in case of any revisions/ change.

44.Will PRIP consider projects that go beyond the scheme's current duration?

Yes, PRIP will consider project that are estimated to hit the market beyond the scheme's current duration. However, the applicant will have to clearly define milestones achievable within the current duration of the scheme and the funding will be provided to the same.

45.Will the funding received under PRIP scheme be taxed?

This would be guided by the applicable tax laws by the Government.

Benefit sharing under component B

46.What are the various benefit-sharing options?

Category B-I and B-II: Benefit sharing applicable to successful technology/ product commercialization starting from first sale of the product/technology.

- 1. Through 10 % benefit sharing on net sale proceeds per year of the product starting from first sale of the product/technology till 10 years
- 2. Through 10% benefit sharing on net sale of the product till amount starting from first sale of the product/technology till the amount is equivalent to 150% of assistance received from DoP
- 3. In the form of equity (face value of shares equivalent to 100% of the assistance provided by DoP)

Category B-III: Benefit sharing applicable to successful technology/ product commercialization starting from first sale of the product/technology.

- 1. Through 5% benefit sharing on net sale proceeds per year of the product starting from first sale of the product/technology till 10 years; or
- 2. Through 5% benefit sharing on net sale of the product till amount starting from first sale of the product/technology till the amount is equivalent to 100% of assistance received from DoP: or
- 3. In the form of equity (face value of shares equivalent to 100% of the assistance provided by DoP)

47.What is the difference between the option 1 and option 2 of the benefit sharing?

Under option 1 the benefit sharing is capped to 10 years with no limit on the amount shared, however the option 2 caps the amount to 100% or 150% (as per the applicable category) without limit on the time of benefit sharing.

48. How is the applicable benefit sharing option decided for each applicant?

Successful applicants will have the option to choose one of the above at the time of signing the agreement.

49.When does the benefit sharing start and what constitutes successful technology/ product commercialization?

- 1. Payment of benefit sharing shall fall due beginning with the first sale of the product(s)
- 2. Success technology/ product commercialization includes:
 - a) Fund recipient directly undertakes market reach of the product/technology.
 - b) Licensing/Assignment/Technology-Transfer of the Project developments to any third party

50.Will the government own / co-own the IP generated in the projects funded by PRIP Scheme?

No, the government will not own / co-own the IP generated in the projects funded by PRIP Scheme. The IP rights will stay with the funded entity or any of their partners as per the IP owner's discretion.

51.Can a fund recipient transfer or sell/ assign the interest of developments?

Yes, the fund recipient can transfer or sell/ assign the interest of developments with prior written permission from Department of Pharmaceuticals

52.What are the implications on benefit sharing if a fund recipient transfers or sells/ assigns the interest of developments?

If the fund recipient licenses the interest of project developments for periodical payments including benefit sharing, then the fund recipient can also continue to share the benefits as prescribed by Department of Pharmaceuticals to be met from the periodical proceeds received from licensees/sub-licensees.

53. When will the benefit sharing be applicable to B III category projects?

If and whenever the projects funded under the B III category generate revenue the benefit sharing will be applicable

Expression of interest process for component B

54. What is the objective of the Expression of Interest?

The EoI has been designed to provide interested entities with an opportunity to co-shape India's journey towards becoming an R&D innovation hub, by soliciting inputs on:

- 1. Current R&D projects in the scheme's priority areas for PRIP funding consideration
- 2. Challenges in execution of an R&D projects
- 3. Actions to strengthen the R&D ecosystem for Pharma and MedTech innovation in India

55.Is it mandatory to fill the EoI form to be able to apply eventually?

EoI is non-mandatory, however interested applicants are encouraged to fill EoI form with details of the project they deem fit to be considered for funding under PRIP. Any kind of project information provided at the EoI stage will not be used for evaluation purposes.

56.Do I need to pay any fee before submitting the EoI?

No, the EoI is open to all interested entities and does NOT entail any fee for submitting responses

57.Will I receive feedback on my EoI submission?

No, there is no formal feedback mechanism for EOIs. The EOI is not evaluated for selection; it's for informational purposes. As such, you should not expect to receive specific feedback or comments on your EoI – there is no scoring or acceptance/rejection at the EOI stage.

58.My project doesn't exactly fit the listed priority areas or categories. Can I still fill the EoI?

Yes – you are encouraged to still apply. The PRIP team understands that some innovative projects may not clearly fit the defined categories or examples. In your EOI (specifically in **Field 3.2** of the form), clearly explain *why* your project does not fall under the existing priority descriptions and make a case for why it should be considered for PRIP funding. Such inputs will be carefully reviewed for inclusion.

59.What does selecting "None" for the benefit sharing preference mean?

The EoI form allows you to select "None" if you do not prefer any of the provided benefit-sharing options. Choosing "None" does not mean you are exempt from benefit sharing; rather, it indicates that the current options don't work for you. If you select "None," you are expected to provide reasons why no option is suitable for your project, and you may suggest an alternative.

60.Can I choose multiple priority areas for my project in the application?

Yes. If your project is relevant to more than one of the defined priority areas, the PRIP **Digital EoI** form allows you to select multiple priority areas when submitting.

Application process for component B

61. How can I apply for funding under the component B?

Applications must be submitted online through the designated portal. This will be shared during the formal 'Call for application'

62. What type of entity registration is needed to apply?

- 1. Pharma or Medtech proprietary, partnership firm, limited liability partnership firm will need to provide PAN number.
- 2. Pharma or MedTech company/ Group of companies will need to provide CIN number issued by Registrar of Companies (ROC) under the Ministry of Corporate Affairs (MCA)
- 3. MSMEs will need to provide Udyam number issued by Ministry of Micro, Small, and Medium Enterprises (MSME)
- 4. Startups will need to provide DPIIT recognition number issued by the Department for Promotion of Industry and Internal Trade (DPIIT)

63.What is the role of Entity Locker in the PRIP scheme?

Under the PRIP scheme, entity authentication will be conducted during the application process through the Entity Locker platform (https://entity.digilocker.gov.in/). Therefore, all interested entities are strongly encouraged to register with Entity Locker in advance of the official 'Call for Applications' to ensure a seamless authentication process.

64. Why do startups need DPIIT registration in the PRIP scheme?

Under the PRIP scheme, authentication for startups will be conducted during the application process through the DPIIT recognition number. Therefore, all interested startups are strongly encouraged to register with DPIIT in advance of the official 'Call for Applications' to ensure a seamless authentication process.

65. What is the application window?

The application window will be open for 45 days. Applications must be submitted within this period; late applications will not be accepted.

66. Can one project application include multiple products, or should each product be submitted separately?

It's generally preferred to focus on a single product per project, for clarity in defining milestones and budgets. However, the scheme does not strictly forbid including multiple closely related products in one application. If your products are closely linked – for example, they share a high percentage of costs and are part of one program – you can justify combining them into one project proposal. You must convincingly present a unified business plan, budget, and set of milestones for the combined project.

67. What is the application evaluation process?

- 1. All applications will be scrutinized to verify the eligibility of the applicants by the project management agency (PMA)
- 2. Eligible applications will be evaluated based on the evaluation parameters specified in Appendix IV of the guidelines. The applicant with the highest marks will be ranked Number 1, followed by others in descending order based on their scores.
- 3. The Technical Committee (TC) will review the applications. The TC will evaluate each application on technical eligibility, including the TRL levels, alignment with the priority areas.
- 4. The Project Appraisal and Approval Committee (PAAC) will finalize the funding decision after eligibility assessment by PMA and review by TC.
- 5. After the PAAC approves the selected applicants based on the defined selection criteria and the available budget for each category. The disbursement process will be initiated, contingent upon the successful submission of required documents and agreements.

68. What are the expected timelines for the evaluation process?

The entire selection process for applications is expected be completed within 90 days from the closing of the application window.

69.Is the information in my EoI/application kept confidential?

Yes – all data and information you submit as part of the PRIP scheme (EoI or full application) will be **kept confidential**. The Department of Pharmaceuticals and its evaluation committee will use your information only for assessment purposes. It will not be shared publicly or with any third parties outside the program's process.