

Biotechnology Industry Partnership Programme (BIPP)

(An Advanced Technology Scheme)



सत्यमेव जयते

**Department of Biotechnology
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Biotechnology Industry Partnership Programme (BIPP)

(An Advanced Technology Science Scheme)

Operational Guidelines

1. What is BIPP?

1.1. The present scheme on **Biotechnology Industry Partnership Programme (BIPP)** is a government partnership with Industries for public support on a cost sharing basis for:

- (i) Path-breaking research in frontier futuristic technology areas having major economic potential and making Indian industry globally competitive and focused on IP creation with ownerships by Indian industry and where relevant, collaborating scientists.
- (ii) The development of appropriate technologies in the context of recognized national priorities in the area of agriculture, health, bioenergy, green manufacturing, when the scale of the problem has serious consequences for social and economic development.

1.2. This is an Advanced Technology Scheme only for high risk, transformational technology/process development. No incremental development will be supported under BIPP.

1.3. Specific priorities have been listed under the different categories. Detailed list of priorities is at **Annexure- I**.

1.4. Category-I: Partnership with industry for fulfilling major unmet national technology needs in health, agriculture, energy and environment friendly/ green manufacturing area.

1.4.1. This is mainly for those areas which are of high natural and social relevance with no assured market such as

- (i) Agriculture- New crops against drought, salinity or major disease and orphan crops of regional interest where private interest is usually low.
- (ii) Rapid development of vaccines, biomarkers drugs, biotherapeutic agents against major infectious diseases that occur as large outbreaks or epidemics (HIV, tuberculosis, malaria, influenza, dengue, etc) and chronic diseases such as diabetes or stroke. The categorization will be based on national disease burden data, emphasizing death and disabling morbidity.
- (iii) Bioenergy sector- cutting edge technology for second generation Biofuel development- Algal Biofuel, Bioethanol etc.
- (iv) Biomedical devices and implants- Indian development of currently imported health devices and equipment that are used on a large scale, (imported ones are in accessible due to cost) and whose use has a life saving impact. Minor use products will not be supported.

1.4.2. This would be more of translational research in such cases it is envisaged that public institutes would be useful partners, so that the basic R&D leads can be translated to product development by the industry.

1.5. Category-II: Partnership with industry for increasing global competitiveness of Indian Industry in new and futuristic technology

- (i) Support for high risk, accelerated technology development specially in futuristic technologies.
- (ii) Only accelerated technology development through transformational change to be supported. No incremental development to be supported. Support is for complete process/technology development leading to high value product commercialization. Some examples are :
- (iii) Nanoscience applications in Medicine and Agriculture,
- (iv) Bio-based energy related advanced biotechnologies,
- (v) Advanced biomaterials,
- (vi) Stem cell biology and tissue engineering,
- (vii) System biology and computational biology,
- (viii) Genomics, proteomics and metabolomics related technologies for futuristic diagnostics
- (ix) Novel manufacturing processes,
- (x) Micro fluidics,
- (xi) Synthetic biology solutions in plant and energy field.
- (xii) Sustainable chemistry and others.

1.6. Category-III: Partnership with Industry for evaluation and validation of already products of high national importance.

1.6.1. To promote innovation in the Biotech Industry specially the SME's sector, it is important to provide support for product evaluation and validation. There are a number of products which are developed by the industry specially the SME's and to accelerate their commercialization support for product evaluation and validation is essential. In case of the biopharma products clinical trials and in case of agriculture products field trials are a critical step in taking the product to the market. Heavy investment is essential to meet increasing stringent global requirement to undertake these activities and the public sector support specially for products of national and societal relevance needs to be provided. Some of the areas where such support is critical are vaccines, public health care diagnostics, biotherapeutics, implants and devices, transgenic etc. **upto 100% grant-in-aid support would be provided for phase-I, II and III clinical trials of biotechnology based research efforts and for limited and large scale field trials in the case of agriculture products provided there is Indian innovation involved in technology development. The grant would not include any Capital investment. SME's as defined by SBIRI (an approved Scheme) would be preferred recipients of support.**

1.7. Category-IV: Shared major facilities around technology platform as core facilities.

1.7.1. Access to major facilities is an essential requirement for success in futuristic technologies and to lay foundations for discovery and innovation. It is our experience that national facilities, established with good intent lack user friendliness and are under utilised. Public-Private partnership is justified for establishment of core facilities to advance research in futuristic technologies and science. An appropriate model is management in the private hands, access to private sector at commercial rates and to the SME sector and public sector at preferred rates. This type of collaboration is already approved by the government for the infrastructure sector.

1.7.2. Some examples are:

- (i) Large animal and transgenics facilities
- (ii) Genomic technology centers / facilities
- (iii) Protein engineering science centres / facilities
- (iv) Chemical and molecular libraries
- (v) Implant and device prototype building labs
- (vi) GMP facilities for cell based product and vaccines
- (vii) Advanced bioinformatics facilities
- (viii) Microbial and pathogenic repositories
- (ix) BSL3-4 facilities

1.7.3. Three different Models are proposed under this:

SNo.	Model	Investment, cost-sharing and sharing of benefits
1.	Government supported – private managed, facility will be located in a National Laboratory and managed by a consortia of industries or a single industry which has no conflict of interest.	(i) 100% grant-in-aid (ii) User charge basis (iii) Ownership with Government (iv) Differential fee for public and private user
2.	Public supported in a public institution in partnership with a private investor who has no conflict of interest	(i) Cost sharing with the industry (ii) Upto 50% grant-in-aid (iii) Shared profits (iv) Ownership will depend on contribution (v) Differential fee for public and private user
3.	Specialized facility for discovery and innovation to be established, operated and managed by a single private industry	(i) Soft loan as per approved SBIRI norms (ii) User charge basis (iii) Differential fee for public and private

		(iv) Should devote a % of time for education and training of DBT identified trainees for capacity building
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2. Who can Apply?

2.1. A single or consortia of Indian “for profit” company (ies)- Small, Medium and Large, involved in R&D. An Indian company is defined as one in which more than 51% ownership is by Indian citizens.

2.2. The proposals can be submitted:

- (i) solely by in-house R&D unit(s) of industrial firms (DSIR recognized)
- (ii) jointly by Industry and National R&D organisations and Institutions
- (iii) collaborative projects of common interest to the concerned sector/or proposed by a group of industries/users, national research organisations etc.

3. Process of idea generation and eliciting of proposal

3.1. There would be wide ranging consultation to generate ideas for cutting edge technologies of national and social relevance and possible solutions, with senior experts, academia and industry. The industry partnership platform established by DBT in partnership with FICCI will be used as a knowledge circle for idea generation in partnership with industry. A Technical Screening Committee which would be area specific will then work on the concept development based on priority areas identified. This concept would then be advertised or if there is limited capacity in the country, the most appropriate company which meet the required criteria would be asked to submit a proposal, along with an academic partner whenever felt necessary.

3.2. The specific priority areas identified would be widely published and proposals invited. The priority areas could change with the advancing technologies and these would be considered and approved by the Apex Committee.

4. How and when to submit proposal?

Proposals would be submitted to DBT/PMU in response to a call for proposal at least 3 times a year. Detailed format for submission of projects will be available on the DBT website. In addition proposals generated through the Industry Platform or Discussion meetings would also be considered.

5. Process of Evaluation

5.1. All proposals would be initially screened for fulfillment of eligibility criteria.

5.2. Thereafter the eligible projects would be evaluated by an area specific Technical Screening Committee (TSC) constituted by Secretary, DBT. The process of evaluation would include peer review, personal discussion and site visit.

5.3. The proposals recommended by the TSC would then be placed before the Apex Committee (AC) constituted by Secretary, DBT for final recommendation. The Apex Committee would decide regarding percentage of cost sharing and also requirements of loan if any.

6. Funding, cost sharing, intellectual property and royalties

6.1. This scheme provides for grant-in-aid by Government to biotech industries ranging from 30-50% for the R&D component i.e. Category I and II and upto 100% for the product evaluation and validation. The Intellectual Property, Technology transfer and licensing arrangements proposed would vary with the model of partnership and cost-sharing. The contribution of the Government and percentage of Royalty would be as per the Apex Committee recommendations based on the Technical Committee's Evaluation. This will be assessed as per defined set of criteria and ranked as high, medium or low.

- (i) Level of innovation
- (ii) Is it an Advanced technology of great promise
- (iii) Is it a Technology of tremendous value for national security and public health
- (iv) Level of risk
- (v) Potential commercial value.

6.2. Sharing of benefits for category I, II & III.

(a) The IP rights belong exclusively to the Industry, in case of other public partners the IP sharing would be on mutually agreed terms among the partners with DBT facilitation.

(b) Industry has the exclusive right of licence for 10 years after commercial release of product, thereafter, the licence becomes non-exclusive. During this period the licence will be held exclusively by the industry in India and it can be licensed outside India only for joint venture.

(c) A royalty of a minimum of 3-7% of net sales to be obtained by the government by way of royalty for itself or for public institutions, which may be ploughed back into the project or used for maintenance of patents or any other related purposes. The percentage of royalty would be dependant on the risk factor involved in the technology / product development as determined by expert members of the evaluation committee based on their aggregate scoring and also percentage contribution by industry partner.

(d) For the support provided by the government for product evaluation and validation, the percentage of royalty would vary from minimum 0.5 to 1% since the product is already developed by the industry. No royalty would be expected for this category from SME's.

(e) During the period that the industry holds exclusively licence, the Government shall have the right to acquire royalty-free licence in India for non-commercial use of the IPR in case of technologies / products of public interest.

(f) The Government would reserve the right to require the licensor to license the technologies / products to others and require that anyone exclusively licensed to market the innovation in India must manufacture the product in India also. The industry would be free to negotiate with the prospective licensee on mutually agreeable terms and conditions. The Government will only facilitate the negotiation if the two parties are not in agreement on any of the terms and conditions.

6.3. Joint Facility-Sharing of Benefits

- (a) User charge basis, profits shared on a case by case basis as decided by the Apex Committee constituted by DBT for the scheme based on proportion of investment.
- (b) Ownership would depend on share of contribution to the cost.
- (c) Differential fees for public and private sector users.

7. How does BIPP differ from SBIRI

The proposed scheme is very different from the ongoing SBIRI, in so much that it targets all industries and not only SME's (SME's as defined by SBIRI, an approved Government Scheme). It is for high risk futuristic technologies and mainly for viability gap funding. The uniqueness of this scheme is that it is for "Break through research" which enables product and process development and is patentable, with IP ownership rights resting with industry. While SBIRI focuses on supporting early stage and pre-proof of concept funding for SME's, the BIPP is proposed for viability gap funding which would enable IP generation. The purpose of SBIRI is different. It provides upto grant-in-aid with a maximum limit of Rs. 50 lakhs and upto Rs. 10.00 crores loan. The proposed BIPP as indicated is for much larger projects of higher cost with a clear deliverable of novel IP generation.

8. Uniqueness of BIPP

- (i) Supports setting up of Joint Research Resource Centres / Facilities in a PPP mode, cost sharing for a publicly funded, privately managed facility - grant to be provided for capital, equipment and operational costs including Manpower.
- (ii) Support for high risk, accelerated technology development specially in futuristic technologies.
- (iii) Only accelerated technology development through transformational change to be supported. No incremental development to be supported. Support is for complete process / technology development leading to commercialization and not limited to just specific events in the commercialization chain eg. Development of a vaccine, transgenic. Improved second / third generation biofuel.
- (iv) Support for very high risk, nationally and socially relevant areas, with no assured market eg. Drought resistant rice or wheat, malaria vaccine. This would be more of translational research in such cases it is envisaged that public institutes would be useful partners, so that the basic R&D leads can be translated to product development by the industry.
- (v) Provides for product evaluation and validation through support for limited and large scale field trial for agriculture products and clinical trials (Phase I, II, III) for health care products.
- (vi) Project should necessarily be for novel IP generation. Innovation is the main criteria IP rights belong to industry.

9. Process of Monitoring and Project Management

9.1. The projects under BIPP will be monitored regularly by an Expert Monitoring Committee (EMC) constituted by DBT one for each project. The monitoring will include detailed personal report presentation and also site visit. The site visits will be conducted by specially constituted Expert Committees comprising two to three Technical experts, one Financial expert and one DBT Office.

9.2. The BIPP Scheme itself would be reviewed during plan mid-term appraisal for changes if any required.

9.3. A Programme Management Unit (PMU) will be set up by DBT for Management and Monitoring of the programme. The PMU will be responsible for management of all Physical and Financial aspects of the programme. The PMU would -

- (i) Arrange idea generation meetings
- (ii) Provide assistance in project formulation
- (iii) Organize meetings of TSC, EMC, AC
- (iv) Organize site visits for each project monitoring
- (v) Follow up/ interact with industry regarding product commercialization
- (vi) Be responsible for release of funds and all other aspects of project management.

10. Terms and conditions and other tools and instruments

A Memorandum of Agreement would be developed to be signed between the Government and Industry which would detail the responsibility of each agency monitoring procedures, timelines, payment schedule and IPR arrangements. The Terms and Conditions mutually agreed upon would be binding on all parties

11. How will funds be disbursed?

The Funds would be provided as grant-in-aid and will cover all Recurring costs for the experimental component. A separate project planning and development grant would be provided to facilitate a detailed project report preparation.

Indicative priority areas for consideration under BIPP

(A) Agriculture Technologies

- (i) Developing nutrient rich staple crop that can be grown under stress condition
- (ii) Drought and salinity tolerant varieties
- (iii) Pest and disease resistant varieties
- (iv) Genetic engineering for industrial product development-Improved enzyme, required levels of energy for alternate energy production, increased starch etc.
- (v) Path breaking technologies for fruits – Apomyxis

(B) Public Health Technologies - Vaccines and Biologicals

- (i) HIV (also microbicides)
- (ii) Tuberculosis
- (iii) Malaria
- (iv) Influenza
- (v) Dengue
- (vi) Pneumococcal
- (vii) Hepatitis C
- (viii) Rotavirus
- (ix) Jap Encephalitis
- (x) Improved Typhoid, Cholera
- (xi) Cancer Vaccines
- (xii) Diabetes, Cardiovascular neurological

(C) Energy Bioscience

- (i) Feedstock development- breeding plant species to maximize cellulosic biomass production.
- (ii) Genomic enabled improved yield and quality.
- (iii) Biomass depolymerisation – cost effective methods for biofuel production.
- (iv) Bioprocess optimization from hydrolysis to fermentation.
- (v) Metabolic pathway engineering to overcome biomass recalcitrance.
- (vi) Improved enzyme and micro-organism products.