

## **BIOTECHNOLOGY INDUSTRY PARTNERSHIP PROGRAMME**

### **Guidelines for disbursement of funds - Category I, II, III & IV**

The Guidelines for disbursement of funds for BIPP as recommended by the Apex Committee are as follows:

1. Level of support to be provided by BIRAC will be in terms of grant-in-aid only
  - i. The financial support by BIRAC would be upto 50 % of the approved Project cost to the Company fund recipient subject to the exemption provided for under 1(iii).

Provided, if the Project proposal has Institute as Academic Collaborator (s) then the total contribution by BIRAC to the Company fund recipient will not exceed the “matching contribution of the Company” as Grant in Aid and the contribution to the Academic Collaborator (s) will be in addition and above to the Grant in-aid of the Company Fund Recipient
  - ii. There is no cap on funding in case of Projects falling under Category I, II & III (Projects of national relevance; Projects involving advanced, high-risk technologies; Clinical trials and agriculture field trials respectively).
  - iii. For conducting phase III clinical trials/ agriculture field trials with high level of innovation and national relevance, the financial support by BIRAC could be up to 75% of the approved Project cost subject to the condition that only the cost of the trial to be conducted within India will be supported. Please note that BIRAC does not intend to become the “Sponsor” in terms of the Rules for the Manufacture, Use, Import, Export & Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989, Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 on provision of funding assistance under the scheme. The funding will be subject to the regulatory compliances by the fund recipient as prescribed under the law of the land.
2. The cost of the Project to be met by BIRAC will be in the form of grant- in- aid having the corresponding obligation of royalty payment (except category IV).
3. The approved funds would be released by BIRAC to the participating industry and collaborating partners in instalments, the first on signing of the Agreement and the subsequent annual instalments on satisfactory progress of the Project in compliance with the agreement as assessed by the Project Monitoring Committee, based on site visit, discussion and Project report.
4. Appropriate Grant Award Letter will be issued by BIRAC for the funds disbursed providing for the governing terms and conditions and these will be accepted by the fund recipient(s) within the time period of four (4) weeks from the date of issue.
5. The templates having the governing provisions shall be provided to the shortlisted applicants at the time of carrying out the site visit. It is to be noted that except for very specific and case dependent technical aspects, the terms and conditions of the funding shall be uniformly applicable on all fund recipients.
6. A separate Royalty Agreement will be entered into between BIRAC and the Company fund recipient(s) for disclosure of the sale of the Product(s) and ensuing royalty. “Product” for this purpose shall mean products, services, processes, technologies, materials, software or other innovations resulting from this Project which would generate commercial income

## 7. ROYALTY GUIDELINES- Payment of Royalty

- i. The Company shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual Net Sales of the product(s) developed with BIRAC's assistance. Payment of royalty shall fall due beginning with the first sale of the product(s) and the liability to pay royalty will terminate upon the first of any of the following two events to occur: - a) 5% royalty has been paid to BIRAC till the royalty amount paid becomes equal to the amount of the Grant-In-Aid disbursed and that was not returned to BIRAC as unutilized funds; or (b) in case of Foreclosure or Termination of Project as per the terms of GLA.

'Net Sales' for this purpose shall mean gross sales by the Company/ its licensee/ its sub-licencee excluding excise duty and sales tax, as certified by the Chartered Accountant.

- i. Royalty for each financial year shall be payable to BIRAC within 60 (sixty) days of close of corresponding financial year.
- ii. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the same Product(s), then the Company shall pay royalty to BIRAC at a cumulative rate of 7 (seven) per cent on annual Net Sales of the product(s) developed with BIRAC's assistance in the same manner as provided above under sub section (i).
- iii. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the distinct Product(s), then the Company shall pay royalty to BIRAC at the rate of 5 (five) per cent on annual Net Sales of each such distinct Product(s) developed with BIRAC's assistance in the same manner as provided above under sub section (i).
- iv. If the Company intends to transfer or sell the Product, it shall take prior written permission from BIRAC and BIRAC will recover the Royalty amount or 5% of the resultant income excluding excise duty and sales tax, as certified by the Chartered Accountant, whichever is less before grant of such permission.

Provided, this Project is not determined as a "Nationally Important Project", to be governed through a specific Order of BIRAC. Such cases of "Nationally Important Project" shall have specific terms of licensing, pricing or March-in-rights for the purposes of public interest/ demand of Government of India.

## 8. Nationally Important Projects

If Apex Committee recommends certain Projects as nationally important Projects, then BIRAC will issue a specific "Order" to make the following provisions applicable;

- A. In such cases of national importance BIRAC shall retain a royalty-free, non-exclusive, irrevocable licence to the Product developed with the funding support of BIRAC with right to sub-license for the purposes of public interest/Government of India and/or as decided by the Apex committee. The licensor of such Product will ensure that where the Product has been produced in collaboration with entities not in receipt of BIRAC's Grant-in-aid, such collaborators will also grant license to

BIRAC in the same way.

B. Nationally Important Projects shall mean such Projects that will serve specific purposes notified by Government of India in public interest.

C. In cases of national importance, if BIRAC determines that such -

- (a) Action is necessary because the Fund Recipient or licensee/s has not taken, within the period of four (4) years from the date of completion of the Project, effective steps to commercialize the Product in such field of use;
- (b) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Fund Recipient or licensee/s;

Then, March-in-rights are applicable whereby;

- i. BIRAC along with retainment of royalty-free, non-exclusive, irrevocable licence to the Product BIRAC, after taking into consideration the fund recipient's requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the Fund Recipient to transfer the technical know-how of the Product developed under the Project to other entrepreneur(s) and train them, on such terms and conditions as may be mutually agreed among BIRAC, the fund recipient and such other entrepreneur(s). Provided, BIRAC shall reserve its right to require that the Product must be manufactured and sold in India.
- ii. If the fund recipient (s) does not agree with the terms of above sub section (i), then BIRAC shall require that all rights and interests associated with the Product including Intellectual Property (IP) Rights to be assigned to BIRAC. The Fund Recipient(s) and co-owners of the IP shall undertake all necessary actions to effect the assignment.

## 9. Category IV (Infrastructure) Funding

The funding assistance under Category IV will be in the form of grant-in-aid without the obligation of payment of Royalty

A. General:

- i. The financial support provided by BIRAC would be subject to a maximum of Rs. 25 crores.
- ii. In cases where BIPP support is restricted to equipment cost only, the first instalment would be released when 80% of the civil/construction work has been completed.

B. For Model I&II:

- i. For a public use facility to be set up by a Company, the Management and Governance Structure should be a well-defined and separate from the Company.
- ii. The company must define the mode of access to the facility by other users.

The funding guidelines for Model I and II have been explained below:

	Model	Investment, cost-sharing and sharing of benefits
I	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 <ul style="list-style-type: none"> <li>• To be levied on direct recipient of benefits from the specific public services,</li> <li>• To be aimed at improving the efficiency of resources and</li> <li>• Not to be less than the marginal cost of supplying the specific public services</li> </ul> (iii) Ownership with Government (iv) Differential fee for public and private user
II.	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 (that means net profits available after tax for sharing) (iv) Ownership will depend on contribution (v) Differential fee for public and private user

	Model	Investment, cost-sharing and sharing of benefits
III	Specialization facility for discovery and innovation to be established, operator and managed by a single private industry	I. Soft loan (Applicable interest rate is 1% per annum if the sanctioned loan amount is upto Rs. 100 lakhs; and 2% per annum if the sanctioned loan amount is above Rs. 100 lakhs) II. User charger basic III. Differential fee for public and private IV. Should devote a % of time for education and training of DBT identified trainees for capacity building

*The repayment of the loan component as well as interest by the industry partner will be in 10 equal annual instalments and recovery would commence six months after the completion of the project as per BIRAC guidelines*