

Biotechnology Industry Partnership Programme (BIPP)
(An Advanced Technology Science Scheme)

**Complete Scheme Document including Proposal Submission, Evaluation
and Review Guidelines**



Department of Biotechnology
Ministry of Science & Technology
Govt. of India

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1. Introduction

Government of India, in November, 2008 approved the implementation of a Public Private Partnership Scheme for promoting innovation research in the Biotech sector. The Biotechnology Industry Partnership Programme (BIPP) was launched in January, 2009.

1.1. What is BIPP?

1.1.1. 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.

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

1.1.3. **BIPP covers four broad categories (I, II, III & IV) as described below:**

Category	Description
I	Areas with major social relevance but uncertain market driven demand
II	High risk, discovery innovation research with relevance for making India globally competitive
III A	Evaluation & validation of already existing products of high national importance promoting local innovation (Clinical Trials)
III B	Evaluation & validation of already existing products of high national importance promoting local innovation (Agriculture Field Trials)
IV	Shared cost major facilities , critical for enabling innovation

1.1.3.1. **Category-I:** Partnership with industry for fulfilling major unmet national technology needs in health, agriculture, energy and environment friendly / green manufacturing area. This is mainly for those areas which are of high national 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.

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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.

1.1.3.2. 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 :
 - a. Nanoscience applications in Medicine and Agriculture,
 - b. Bio-based energy related advanced biotechnologies,
 - c. Advanced biomaterials,
 - d. Stem cell biology and tissue engineering,
 - e. System biology and computational biology,
 - f. Genomics, proteomics and metabolomics related technologies for futuristic diagnostics
 - g. Novel manufacturing processes,
 - h. Micro fluidics,
 - i. Synthetic biology solutions in plant and energy field.
 - j. Sustainable chemistry and others.

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

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. 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. SME's as defined by SBIRI (an approved Scheme) would be preferred recipients of support.

Category III is further sub-divided into:

- Category IIIA (Clinical Trials)
- Category IIIB (Field Trials)

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

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 underutilized. 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.

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Some examples are:

- a. Large animal and transgenics facilities
- b. Genomic technology centers / facilities
- c. Protein engineering science centres / facilities
- d. Chemical and molecular libraries
- e. Implant and device prototype building labs
- f. GMP facilities for cell based product and vaccines
- g. Advanced bioinformatics facilities
- h. Microbial and pathogenic repositories
- i. BSL3-4 facilities

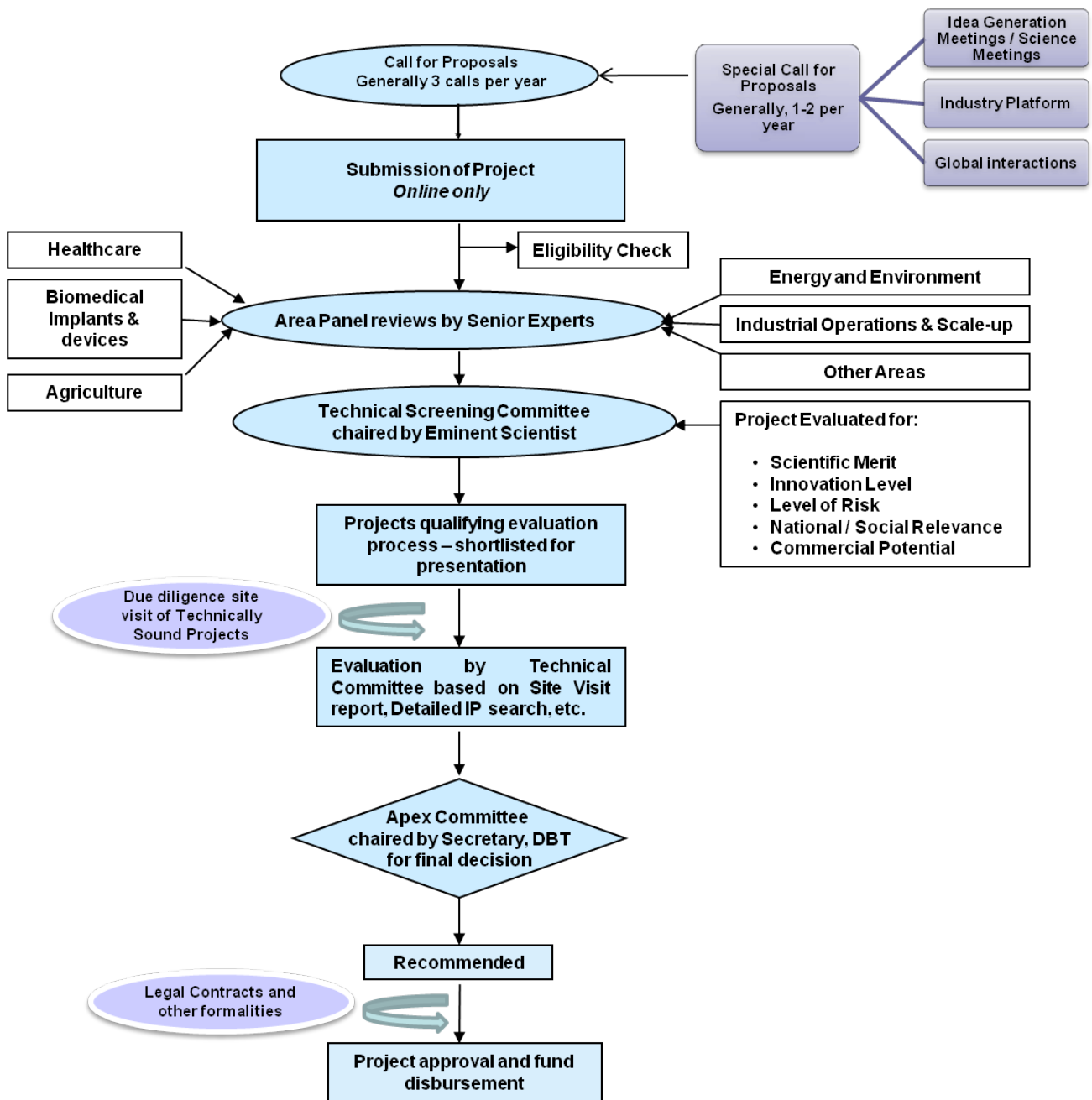
Three different Models are proposed under this

S. No.	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	<ul style="list-style-type: none"> ➤ 100% grant-in-aid ➤ User charge basis ➤ Ownership with Government ➤ Differential fee for public and private sectors
2.	Public supported in a public institution in partnership with a private investor who has no conflict of interest	<ul style="list-style-type: none"> ➤ Cost sharing with the industry ➤ Upto 50% grant-in-aid ➤ Shared profits ➤ Ownership will depend on contribution ➤ 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	<ul style="list-style-type: none"> ➤ Soft loan ➤ User charge basis ➤ Differential fee for public and private ➤ Should devote a % of time for education and training of DBT identified trainees for capacity building

1.2. Uniqueness of BIPP

- ☞ Support for high risk, accelerated technology development especially in futuristic technologies.
- ☞ 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 e.g. Development of a vaccine, transgenic. Improved second / third generation biofuel.
- ☞ Support for very high risk, nationally and socially relevant areas, with no assured market e.g. 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.
- ☞ 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.
- ☞ Project should necessarily be for novel IP generation. Innovation is the main criteria IP rights belong to industry.

BIPP – Operational Mechanism



Process of Evaluation / Decision Making takes 4-5 months. Decision is conveyed at each stage.

2. Proposal Submission

2.1. Who can Apply?

A single or consortia of Indian "for profit" company(ies) - Small, Medium or Large having DSIR* recognized in-house R&D unit(s). An Indian Company is defined as one which is registered under the Indian Companies Act 1956 and in which more than 51 % of the ownership is held by Indian Citizens (including NRIs). The proposals can be submitted:

- solely by an Indian Company; or
- jointly by an Indian Company and National R&D Organizations and Institutions; or
- by a group of Indian Companies along with National Research Organizations etc.

*(*The companies in the process of obtaining DSIR recognition may also apply along with the proof of application to DSIR. However, the final decision on such applications would be subject to their getting DSIR recognition)*

2.2. Process of idea generation and eliciting of proposal

2.2.1. Wide ranging consultations are held 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 is also used as a knowledge circle for idea generation in partnership with industry. A Technical Screening Committee, which is area specific then works on the concept development based on priority areas identified. This concept is then advertised or if there is limited capacity in the country, the most appropriate companies which meet the required criteria are asked to submit a proposal, along with an academic partner whenever felt necessary.

2.2.2. The specific priority areas identified are 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.

2.3. How and when to submit proposal?

Proposals are required to be submitted online only. Online proposal submission can be done by registered company users only during an active call. Generally 4 calls are advertised each year. Special calls on identified priority areas are also advertised. Process for submitting the proposals online is detailed below:

- Log on the BIRAP website (www.birapdbt.nic.in)
- If you are a registered user, log-in using the credentials, else you need to register your company with by clicking on New User Registration.
- In case of new user registration, a computer generated password would be sent to the email-id provided at the time of registration. The password can be changed later.
- Once you login, you would be navigated to the page displaying BIPP link.
- Click on the BIPP link under Programmes and the active call would be highlighted.
- Click on the active call against which you wish to submit the proposal.
- Further details on How to submit a proposal would be available in the BIPP User Guide available on the website.

Company User Registration is open round the clock.

Online Proposal Submission can be done only during an active call.

(Advertisement for Call for proposals is released in all national dailies and some biotechnology related magazines. Intimation of an active call is also displayed on the DBT, BIRAP and BCIL websites)

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- 2.4. Details on How to submit a proposal are available in the **BIPP User Guide (Annexure I)**

Information can also be obtained on

http://dbtindia.nic.in/uniquepage.asp?id_pk=680

<http://www.birapdbt.nic.in/programmes.php>

- 2.5. Pro forma for Submission of Proposal **may be seen at**

http://dbtindia.nic.in/uniquepage.asp?id_pk=680

<http://www.birapdbt.nic.in/programmes.php>

3. Evaluation and Decision Making

3.1. Process of Evaluation

The process of evaluation broadly comprises the following steps:

- i. Peer Review by a Panel of area-specific experts called as **Area Review Panels (ARPs)** created for evaluation.
- ii. Presentation for technically sound projects to the Technical Screening Committee (TSC), comprising eminent scientists from all over the country
- iii. Site Visit for the projects shortlisted by the TSC
- iv. Expert Review, wherever required
- v. Final review by TSC and scrutiny and decision by the Apex Committee comprising Senior Technical Experts of members from various ministries and Government departments and chaired by the Secretary, DBT.

3.2. Role and Responsibility of the Reviewer and Expert Member

Specific role of the Expert Reviewer of different panels is to:

- i. Review the project online and give a detailed evaluation based on the established criteria.
- ii. Shortlist proposals based on Review score for a detailed presentation.
- iii. Assess proposals based on the interaction during the presentation and shortlist for an on-site visit.
- iv. Technical Due diligence during on-site visit after detailed interaction with Applicant.
- v. Recommend proposals for support under BIPP after Technical Screening Committee discussion.
- vi. Assist the Department of Biotechnology in Monitoring the Project.

3.3. Guidelines for Reviewers and Panel Members

3.3.1. The evaluation process is completely online and comprises following 4 level reviews:

- i). **Initial Peer Review- Area Review Panel (ARP)**
- ii). **Technical Screening Committee**
- iii). **Site visit and Due Diligence – (Technical & Financial)**
- iv). **Apex Committee**

3.3.2. There are different subject specific “**Scientific/Technical Evaluation Panels**” one each for the areas namely Agriculture, Healthcare, Health Biotechnology - Product Validation, Energy, Environment and Industrial Operations. Reviewers are senior scientists / experts in the relevant subject area and each reviewer signs a confidentiality certificate while accepting to be associated with the review process.

3.3.3. The Reviewers are assigned proposals along with a brief summary to get a feel of the project and to form an opinion about any conflict of interest. Those experts who have **No conflict of interest** with the applicant and/or the proposals and sign the certificate are then given full access to the proposal.

3.3.4. The proposals are evaluated based on following criteria:

- a. Scientific Merit
- b. Innovation Level
- c. Level of Risk
- d. National / Social Relevance
- e. Commercial Potential

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3.3.5. Each reviewer is required to prepare a written critique for each application assigned based on the review criteria and allot scores for each defined parameter and sub parameters in the prescribed format. The reviewers would maintain complete confidentiality about the proposals. The reviewers are generally given two weeks for proposal evaluation and submission of report. The evaluations of the reviewers are then discussed by the Technical Screening Committee (TSC). The coordinator of each of the Review Panel would serve as the moderator for that area and would discuss and normate scores for the proposals for which there is a significant variation in the scores allotted by the reviewers. The Technical Committee then discusses each proposal finally after moderating. The Technical Screening Committee (TSC) shortlists proposals for next round of screening i.e. Presentation. During the presentation a detailed discussion is held and proposal are evaluated for the following.

- a. Level of innovation
- b. Advanced technology of great promise
- c. Technology of tremendous value for national security and public health
- d. Level of risk
- e. Potential commercial value

Each is ranked as high, medium and low.

Evaluation Formats are at Annexure II

These may also be seen at

http://dbtindia.nic.in/uniquepage.asp?id_pk=680

<http://www.birapdbt.nic.in/programmes.php>

3.4. Guidelines to Reviewers regarding Confidentiality and Conflict of Interest

- In discharging their duties as Panel members, all Panel members must observe the Code of Conduct, Conflict of Interest and Confidential Information requirements set out below.
- These guidelines apply equally to everyone involved in the assessment of applications – including, but not limited to Panel members and Reviewer.

3.4.1. Confidentiality and Transparency

An effort has been made to ensure complete transparency in the proposal submission and evaluation. An important feature of the BIPP process is the high level of confidentiality which is maintained throughout the proposal decision making process.

The review panels and technical committees are comprised of senior technical experts and eminent scientists from research institutions, academia and public sector.

Each member signs a confidentiality certificate before having access to any document related to BIPP proposals. Issues related to conflict of interest are specially taken care of and each reviewer declares a no conflict before they can access any documents. The entire process is online.

DBT receives applications under BIPP in confidence and is responsible for protecting the confidentiality of their submission and contents. For this reason, confidentiality must be maintained; therefore, DO NOT copy, quote, or otherwise use material from this summary application. When you

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have completed the review, please destroy all printed and electronic materials related to the application and maintain its confidentiality. If you are unable to review, please do not accept the Membership online. You can click on Not Available or state Conflict of Interest when it asks for your consent and destroy all printed and electronic materials related to the application, and maintain its confidentiality.

Any panel member can self reveal the fact that he/she served on the panel, but CAN NOT reveal the composition of the panel or any of the discussions during the panel meeting or during the entire review processes.

3.4.2. Conflict of Interest: These guidelines are designed to ensure that all such conflicts are:

1. Identified and disclosed;
2. Recorded; and
3. Managed in a rigorous and transparent way that promotes public confidence in the integrity, legitimacy, impartiality and fairness of the Panel's decision making process.

What is a Conflict of Interest?

A conflict of interest usually involves a conflict between the public duty and the private interests of a member, in which the member has private interests which could improperly influence the performance of their official duties and responsibilities.

These guidelines apply not only to actual conflicts of interest but also to 'apparent' or 'perceived' conflicts of interest. This kind of conflict of interest arises when it *appears* that the member has private interests which could improperly influence the performance of their official duties and responsibilities.

These guidelines also apply to 'potential' conflicts of interest. This kind of conflict is one which may not have yet occurred but if the Panel member were to become involved in certain relevant activities an actual, or apparent conflict could arise.

Conflict of interest may arise in respect of a particular application in the following situations (this list is indicative and not exhaustive):

- the involvement of a Panel member in any current application – eg. as an applicant for funding or as the supervisor of an applicant;
- membership of a Panel member in an organisation involved in any current submitted application under the programme; or
- ownership of shares by an Advisory Panel member in a company involved in any current, established or submitted application, or if the future of the company will be significantly affected by the success of the application.

Note: a conflict of interest may also exist where a member's spouse or immediate family member has any of the interests or involvements listed above.

You must disqualify yourself as a reviewer of an application if you have had any conflict of interest in the project including the following:

- a. Had a consulting/financial arrangement or other conflict of interest in the past 3 years, including receiving compensation of any type (e.g., money, goods, or services)

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- b. Have a known family relationship such as a spouse, child, sibling, or parent, or other relationship, such as a close personal friendship, that you think might affect your judgment or be seen as doing so by a reasonable person familiar with the relationship.

Guidelines for Confidentiality and No Conflict of Interest are at Annexure III

4. Funding, Cost Sharing & IP Management

- 4.1. This scheme provides for a BIPP contribution of upto 50% of project cost remaining cost is to be met through the company's contribution. The grant-in-aid by Government to the company ranges from 30-50%, the BIPP remaining BIPP contribution is in the form of Loan. The contribution of the Government is as per the Apex Committee recommendations based on the Technical Committee's Evaluation. This is assessed as per defined set of criteria mentioned below and ranked as high, medium or low:

- a. **Level of innovation**
- b. **Advanced technology of great promise**
- c. **Technology of tremendous value for national security and public health**
- d. **Level of risk**
- e. **Potential commercial value.**

The Intellectual Property, Technology transfer and licensing arrangements proposed would vary with the model of partnership and cost-sharing.

The fund disbursement is milestone based and is released in 5 instalments:

1 st Instalment on signing of Contract	-	30%
2 nd Instalment on completion of 1 st Milestone	-	20%
3 rd Instalment on completion of 2 nd Milestone	-	20%
4 th Instalment on completion of 3 rd Milestone	-	20%
5 th Instalment on Submission of Report	-	10%

Detailed Guidelines for Disbursement of funds are at Annexure IV and may also be seen at:

http://dbtindia.nic.in/uniquepage.asp?id_pk=680

<http://www.birapdbt.nic.in/programmes.php>

4.2. Sharing of benefits(IP)

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 through DBT's facilitation. The IP clause as per the Agreement to be executed reads as follows:

- i. *"It is the responsibility of the Company to protect the New Intellectual Property (IP). It shall bear the expenditure involved in protecting the New IP. For the purpose of this Agreement, New IP means intellectual property generated during the conduct of the Project by the Company excluding the intellectual property generated by the Company before execution of this Agreement and any new IP generated outside the scope of this Agreement even during the term of this Agreement.*
- ii. *New IP is the sole property of the Company. However it shall be a joint property of the DBT and the Company till full and final settlement of all dues to the satisfaction of DBT. During this period, the Company shall not assign or transfer the New IP to any third party directly or indirectly without prior written consent from DBT."*

4.3. Royalty clause - Payment of Royalty

The Company shall pay royalty to DBT at the rate of 5 (five) per cent on annual net sales of the product developed with DBT's assistance. Payment of Royalty shall be due beginning with the first

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sale of the product and the liability to pay royalty will terminate upon the first of any of the following three events to occur:- a) 5% Royalty had been paid to DBT for a period of five (5) years; (b) The Royalty amount paid to the DBT becomes equal to twice the amount of the grant-in-aid disbursed or (c) in case of foreclosure in accordance with Clause 9.

'Net Sales' for this purpose shall mean gross sales excluding excise duty and sales tax, as certified by the Chartered Accountant. Royalty for each financial year shall be payable to DBT within 60 (sixty) days of close of corresponding financial year. In case of delay in payment of royalty, the Company shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum on the amount of default in payment of royalty for the period of delay.

5. Project Monitoring & Mentoring

5.1. Project Monitoring Committee (PMC)

The projects under BIPP are monitored/and mentored regularly by an Expert Committee constituted by DBT for each project. Site visits are conducted by specially constituted Expert Committees comprising two to three Technical experts and one Financial expert. The Project Monitoring Committee (PMC) is responsible for

- i. To monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives as contained in the Agreement.
- ii. To keep track of funding from any other source for the particular Project.
- iii. To assess the global developments impacting the domain of the Project.
- iv. Based on the foregoing, to assess and suggest:
 - a. recommend the release of next instalment or part release thereof by the DBT.
 - b. recommend revision of project duration
 - c. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - d. inclusion of additional industrial/institutional partner(s), if the Company request involvement of such partner(s), in the overall interest of the Project,
 - e. mentor(s) to assist in overcoming any technological problem faced in the Project implementation; and
 - f. revision of the financial assistance.
- v. To advise on issues related to securing of IPR; and
- vi. To advise on any other matter as referred to it by DBT/BMA and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of BIPP Scheme.

5.2. Reporting of Progress:

- 5.2.1. On Successful completion of each Monitorable Milestone the Company and other Partners are required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
- 5.2.2. The MCR is assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.
- 5.2.3. Each partner has to submit a Statement of Expenditure for the Budget available for the specific milestone being reported upon. Both Company and BIPP Contribution are to be accounted for.

Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure are at Annexure V.

6. Terms & Conditions and Requisites for Fund Disbursement

6.1. Agreement of funding

On announcement of Award, all concerned applicants need to sign an Agreement for Funding with Department of Biotechnology, Government of India.

Agreement Templates:

- i). [Template for Grant \(DBT + Company\)](#)
- ii). [Template for Loan \(DBT + Company\)](#)
- iii). [Template for Grant and Loan \(DBT + Company\)](#)
- iv). [Template for infrastructure/category IV \(DBT + Company\)](#)
- v). [Template for Grant \(DBT+Company+ Institution\)](#)
- vi). [Template for Loan and Grant \(DBT+Company+ Institution\)](#)

6.2. Other Requisites for Funds Disbursements to Company

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

6.2.1. A Board Resolution needs to be passed for acceptance of the Grant and/or Loan offer by the DBT under BIPP

6.2.2. Opening up a No-Lien Account with a scheduled/nationalized Bank

6.2.3. Executing Deed of Hypothecation or providing Bank Guarantee as a mode of security
(This does not apply in case the complete funding is in the form of Grant-in-aid)

All the above tools and instruments may be seen at:

http://dbtindia.nic.in/uniquepage.asp?id_pk=680

<http://www.birapdbt.nic.in/programmes.php>

7. Contact Information

Further information can be obtained at

DBT Website: www.dbtindia.nic.in (http://dbtindia.nic.in/uniquepage.asp?id_pk=680)

BIRAP Website: www.birapdbt.nic.in (<http://www.birapdbt.nic.in/programmes.php>)

Contact Person

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