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BIPP: Fuelling Innovation

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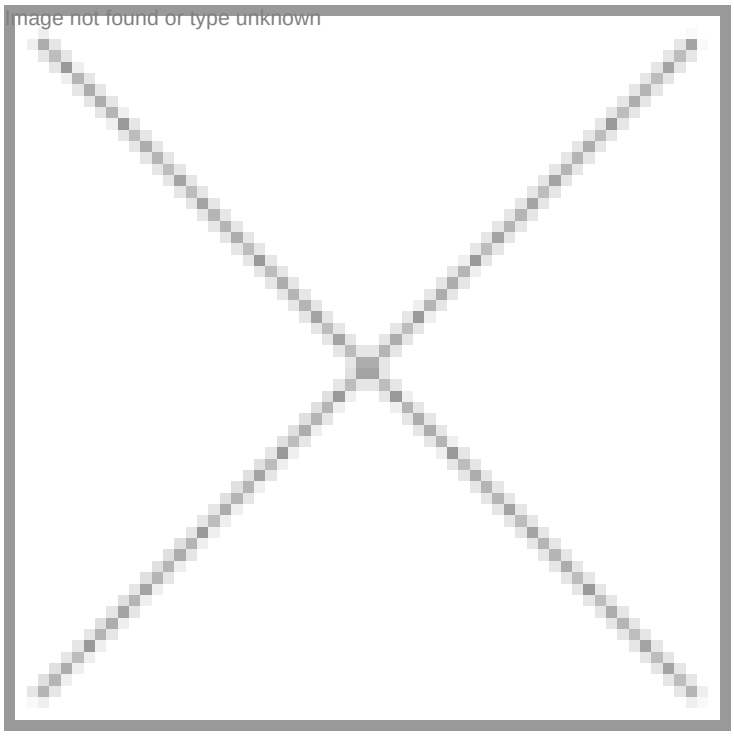


BIPP: Fuelling Innovation

The BIPP scheme approved by the cabinet recently proposes to give a fillip to innovation and R&D in biotechnology by promoting partnerships with the industry...

It was a year ago when the National Biotech Development strategy envisaged the formation of a Biotechnology Industry Partnership Programme or BIPP, an advanced technology science scheme, where the government would partner with industries for support on cost sharing basis for high-risk discovery and innovation and accelerated technology development especially for futuristic areas. On November 6, 2008, the Cabinet Committee on Economic Affairs (CCEA) gave its approval for BIPP setting aside an amount of Rs 350 crore for the scheme during the 11th Plan thus paving the way for technological development and innovation in Biotechnology.

As a principle, BIPP would strictly promote high risk, transformational technology/process development. No incremental development will be supported. On a broad basis, it is directed at 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. To fulfill the biotech strategy objectives of 30 percent of DBT's R&D investment in partnership with industry under BIPP support would be in four major categories.

Category-I

Partnership with industry for fulfilling major unmet national technology needs in health, agriculture, energy and environment friendly/green manufacturing areas. This is mainly for those areas, which are of high natural and social relevance with no assured market such as:

- Agriculture-New crops against drought, salinity or major disease and orphan crops of regional interest where private interest is usually low.
- 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.
- Bioenergy sector-Cutting edge technology for second-generation biofuel development like algal biofuel and bioethanol.
- Biomedical devices and implants- Indian development of currently imported health devices and equipment that are used on a large scale, (imported ones are inaccessible due to cost) and whose use has a life saving impact. Minor use products will not be supported.
- Translational research can also be supported to translate basic R&D to product development by the industry if it is envisaged that public institutes would be useful partners.

Category-II

Partnership with industry for increasing global competitiveness of Indian Industry in new and futuristic technology. This would again support process/technology development leading to high value product commercialization specially in futuristic technologies such as nanoscience applications in medicine and agriculture, bio-based energy related advanced biotechnologies, advanced biomaterials, stem cell biology and tissue engineering, system biology and computational biology, genomics, proteomics and metabolomics related technologies for futuristic diagnostics to name a few.

Category-III

Partnership with industry for evaluation and validation of products of high national importance. This is to promote innovation in the SME's sector by accelerating the commercialization support for their product evaluation and validation, since it requires a heavy investment to meet increasing stringent global requirements to conduct clinical trials for Pharma products and field trials in case of agriculture products. 100 percent grant-in-aid support would be provided for phase-I, II and III clinical trials of biotechnology based research efforts, 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.

Category-IV

Shared major facilities around technology platform as core facilities. 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 could include large animal and transgenics facilities, genomic technology centers / facilities, protein engineering science centers / facilities and chemical and molecular libraries to name a few.

Idea generation

It has been proposed that 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 (TSC), 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. The specific priority areas identified would be widely published and the proposals are invited. The priority areas could change with the advancing technologies and these would be considered and approved by the apex committee.

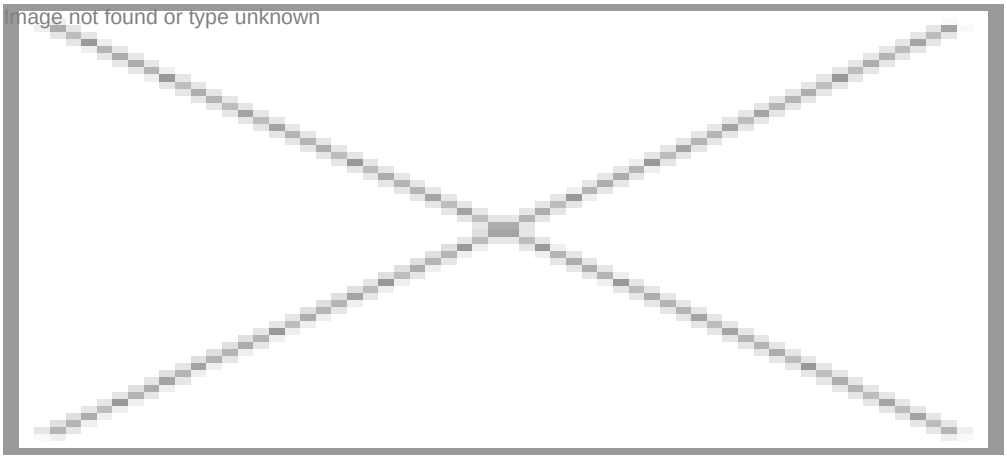
Evaluation

All proposals would be initially screened for fulfillment of eligibility criteria and after which the area specific technical screening committee constituted by Secretary, DBT, would evaluate the eligible projects. The process of evaluation would include peer review, personal discussion and site visit. The proposals recommended by the TSC would then be placed before the apex committee constituted by Secretary, DBT for final recommendation. The apex committee would decide regarding percentage of cost sharing and also requirements of loan if any.

Funding, cost sharing, IP and royalties

This scheme provides for grant-in-aid by government to biotech industries ranging from 30-50 percent for the R&D component i.e. Category I and II and 100 percent 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. Some of the points of considerations will be: level of innovation, an advanced

technology of great promise, a technology of tremendous value for national security and public health, level of risk and potential commercial value.



Sharing of benefits

- 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.
- Industry has the exclusive right of license for 10 years after commercial release of product. Thereafter, the license becomes non-exclusive. During this period the license will be held exclusively by the industry in India and it can be licensed outside India only for joint venture.
- A royalty of 3-7 percent 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.
- For the support provided by the government for product evaluation and validation, the percentage of royalty would vary from 0.5-1 percent since the product is already developed by the industry. No royalty would be expected for this category from SMEs.
- During the period that the industry holds exclusively license, the government shall have the right to acquire royalty-free license in India for non-commercial use of the IPR in case of technologies / products of public interest.
- 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.
- For joint facilities the profits will be shared on a case-by-case basis as decided by the Apex Committee constituted by DBT for the scheme based on proportion of investment.

The ownership would depend on share of contribution to the cost with differential fees for public and private sector users.

Monitoring and Project management

An Expert Monitoring Committee (EMC) constituted by DBT, one for each project, will regularly monitor the projects under BIPP. The monitoring will include detailed personal report presentation and also site visit. Specially constituted Expert

Committees comprising two to three technical experts, one financial expert and one DBT officer will conduct the site visits.

The BIPP Scheme itself would be reviewed during plan mid-term appraisal for changes if any required. 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 arrange idea generation meetings, provide assistance in project formulation, organize meetings of TSC, EMC, AC, organize site visits for each project monitoring, follow up/ interact with industry regarding product commercialization and be responsible for release of funds and all other aspects of project management.