

## "We want Indian Biotech industry to get a new dimension"

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*Dr M K Bhan, who's been at the helm of formulating the National Biotech Development Strategy, gives us a clear view on BIPP and its purpose. Here are the excerpts from the interview with him.*

### **What was the idea behind setting up BIRAC?**

We wanted to change the role of DBT so that it is directly and effectively an instrument of R&D and innovation within the companies particularly SMEs. What we did with BIRAC is to say that we create a new organization, which has DBT, ABLE, BCIL as core partners. Their role in BIRAC is independent of their role as an organization. This organization (BIRAC) is distinct from all organizations and it has its own entity and own purpose, which is unique to it.

We are doing two things here. We are creating two organizations. DBT, which is the national funding agency, funds all kinds of life sciences research. We will create an agency, which will become the innovation management agency of the government in biotechnology. This agency is BIRAC. So BIRAC will not only operate our industry R&D schemes, it will provide innovation link service, tech transfer, IP, service support and advice for new companies, provides regulatory advice, clinical trials support and field trials thus covering the whole value chain. DBT will manage the science function and BIRAC, the innovation management. 30 percent of DBT's budget in future will be spent through BIRAC and 70 percent through DBT. This is our goal and we have to move towards it.

### **What would be the priority areas that BIPP would concentrate upon?**

First of all the project has to be innovative. For example, a novel platform for diabetes, a novel way of delivering cancer drugs, a new way of designing immunogens for vaccines, a new manufacturing process, in short something that will be innovative for future, a generic technology that will have wide effects like drug discovery through systems biology, biomarkers, gene therapy, and stem cell therapy to name a few. It has to be something that we don't do well now and that cannot be done through a usual kind of a partnership. It has to be something that a company won't go easily into because of its high complexity. We shall be measuring selection of the projects by their potential. We are looking for novel things, substantial innovation and unique applications with transformational results. For instance, a project to find out a marker that can tell which TB drug can proceed with development and which should be exited. We are going to look at new scientific hypothesis, new materials and new technologies.

### **How is BIPP different from SBIRI?**

SBIRI is in its early stage. The projects require small initial resource. In BIPP, projects that succeed in SBIRI could apply and also those which don't fit into the budget of SBIRI. BIPP covers the whole value chain from early stage to late development right through to commercialization. It will look at those projects that require larger resources and demand more in terms of originality, novelty and potential value. SBIRI encourages a wide variety of people to try out a number of things. BIPP is focusing on grand challenges. We want Indian Biotech industry to experience things they would not normally do. However, we are also pragmatic in our approach and we will also support those ideas that do not succeed beyond a certain point. For instance, every vaccine nowadays, stops at Phase I or Phase II, because no one has money to go beyond that, so we are creating our fund to facilitate that. Many SMEs who have NCEs or new vaccines won't go ahead with international partnerships because the risk is too much, so we will partner with them all the way if we see that they have the capacity. SBIRI is our early stage support scheme, BIPP, would concentrate on big science, big innovations, where governments job would reduce/cover their risk.

### **Will BIPP aim at fulfilling a social purpose while generating IP and promoting R&D?**

We have also combined a social purpose. There has to be a way of thinking about India based solutions that can make a difference. We are going to heavily use our experience and information and knowledge by talking to multiple stakeholders to really design solutions for Indian health in a meaningful way. That's what we meant when we mean when we say, "it is not about advanced science and technology, but unique solutions for big national problems". As for IP, when you do this kind of research, you do not get the product immediately, but a patent first. So the outcome of this kind of research is not just producing a product, as we see it; it is also producing novel, high value IP.

### **How about the funding?**

We are working with our apex committee (in the next one-month) to create SOPs and provide clarity. We are taking some hypothetical case studies, and will be doing a mock drill on a variety of projects that will come to find out how best can we deal with the projects and ideas that come in. We have given the broad guidelines for funding and there will be refined operational guidelines for the scheme on how it spans out in practice within a month's time frame.

### **What are the challenges that you foresee in putting BIRAC in place?**

Our challenge is that we have to build that capacity (BIRAC) because it does not exist. Deciding when to charge royalty and how much is another issue. We need to have a fair scheme and have transparency, openness and avoid conflict of interest. Further, we need to support these projects and develop contracts and agreements, build a brand of officers in BIRAC who know how to do innovation management as against funding. We have to find new people and train old people to do this. So

corporate management, helping them use research resources and problem solving is a challenge. We want a BIRAC officer to be a partner and a monitor at the same time and yet not be intrusive.

We require to build diverse skills for this. We will require people who can support small companies with clinical trials, writing documents, map out resources and consultants in India and abroad, and do the risk evaluation of projects. Since the investment per project will be large, and being high science projects that companies propose, the degree of skill and manpower has to be high since the companies themselves will be working at the edge of their own abilities. The danger is to oversimplify the challenge in handling such systems, both for the industry and for us. We haven't put in a huge amount of money as yet because we are not sure about the demands. We started with Rs 350 crore and with the passage of time we will put more into it if its worth it.

Shalini Gupta