DST and the earmarked fund for pharmaceutical research and development

The Planning Commission has allocated Rs 150 crore as a corpus R&D promotion fund for the drug industry in the Tenth Plan period. The Department of Science and Technology (DST) has already been assigned to operate this fund. V. S. Ramamurthy, Secretary DST, when asked to elaborate on how he intends to do so, said that that two options lay before him which would be concretized in the forthcoming meeting with the Pharmaceutical Research and Development Committee chaired by R. A. Mashelkar, Secretary DSIR and Director General, CSIR due to be held shortly. One of the options is to strengthen the existing 'Drugs and Pharmaceuticals Research Programme' of DST, and the other would be to operate the fund with an approach that would have its genesis in the recommendations of the Pharmaceutical Research and Development Committee Report. The first option has the track record of Technology Development Board of DST already investing about 30% of its resources in drug and pharmaceutical research, according to Ramamurthy. He further felt that the total allocation of Rs 150 crore was too small a funding for a period of five years, and without a cess levied on products, would amount to nothing at all. However, he added that the fund would be linked to industry for choice of determining eligibility, with the exact modalities yet to be worked out.

Speaking on the first option and DST's own Drugs and Pharmaceuticals Research Programme, Ramamurthy said that since its inception in 1994–1995, DST had committed about Rs 23.3 crore and the industry a sum of Rs 29.6 crore that has supported 38 ongoing projects among which 9 have been completed. The initial hiccups in the early years such as maintaining strict confidentiality, having personnel committed to the project and a fixed time-frame committed budget had all been dealt with.

The programme supports research in all systems of medicine and helps in setting up national facilities. So far only four facilities have come up. These are the following:

- Combinatorial chemistry cum high throughput screening facility at Central Drug Research Institute (CDRI), Lucknow.
- Pharmacological testing facility, CDRI, Lucknow.
- Evaluation of immunomodulating potential of products and extracts of natural origin facility, Indian Institute of Chemical Biology, Kolkata.
- Characterization of crystals of biological macromolecules of medicinal and industrial importance facility, Indian Institute of Science, Bangalore.

In terms of output of the programme, one peptide-based anti-cancer drug that could be used in the treatment of colorectal cancer is to undergo human clinical trials. Three product patents based on two projects and about twelve process patents based on four projects have been filed, but none granted. The break-up of participating collaborators are 17 industries, nine laboratories and nine from academia; among these the latest addition is Saurashtra University, Rajkot.

At present the programme has a 50 : 50 sharing of financial requirements between industry and institution, with research undertaken by the industry being wholly financed by them. On the other hand, institutional share has support from both government and industry with capital expenditure being fully financed by the government and recurring expenditure shared in the ratio 70 to government and 30 to industry.

Some bottlenecks in drug development which are significant and which the government needs to look at are the clearances that have to be taken from a multitude of Ministries, each dealing with a particular clearance necessary for a drug to see the market place from the laboratory bench. This coupled with delay in replies to clearance-seeking letters worsens the morale of researchers. It might be a better idea to incorporate a finite time for clearance and make regulators answerable for delays. For streamlining the whole process of drug discovery and development, India has a requirement for a greater number of clinical research laboratories/testing laboratories that could cater on demand, for a price, in the private sector. This would help speed-up the process of obtaining clearances, important, if one has to remain competitive.

The second option open to DST is under the charter of the recommendations of the Pharmaceutical Research and Development Committee (PRDC). Among the various recommendations of the Mashelkar PRD Committee are that a company or a firm to qualify as R&D-intensive company in India for price benefits should meet the following conditions such as invest at least Rs 10 crore per annum in innovative research, including new drug development, new delivery systems, etc. in India; employ at least 100 research scientists in R&D in India (a scientist as defined by the Department of Scientific and Industrial Research is a person having qualifications and training in science and engaged in basic or applied R&D, non-routine testing and analysis, design engineering, R&D project planning and control, and intellectual property and technology management); has been granted at least 10 patents for the research done in India before filing an application, and owns and operates manufacturing facilities in India.

According to the Committee, 'the intention of setting the above "gold standards" is to ensure that in India, we will fuel the emergence of firms, who are deeply committed to innovation and demonstrate this commitment by

- enhancing the financial inputs in R&D,
- switching over to cutting edge and frontline innovative new drug development research, rather than just imitative research,
- creating significant employment opportunities for Indian scientists who do not have such adequate challenging opportunities in R&D today,
- raising the Indian standards of manufacture to contemporary international levels, and
- creating a strong IPR culture in the firms.

The committee recognizes that none of the firms in India today meet all the above criteria. However, it is hoped that by providing such stimuli, it would be possible for them to move on the path of becoming R&D-intensive, quality conscious, indigenous contenders to global players.'

It is still left to be seen how the earmarked fund for pharmaceutical research and development is used.

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