



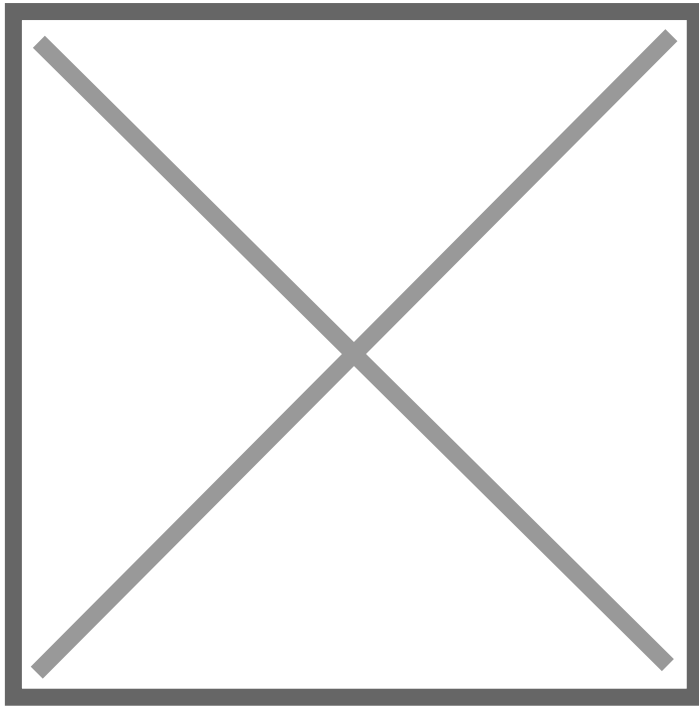
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ABLE'S Recommendations For Budget 2006

06 January 2006 | News



ABLE'S Recommendations For Budget 2006

Pre-VC financing for biotech products: There exists a critical funding gap between "Concept to Proof-of-Concept" after which VCs can take over. It is therefore recommended that Budget 2006 provides for the following initiatives:

Equipment Used in Biotech

Production

- Animal cell culture fermenter
- Automatic closing machine
- Automatic filling machine
- Automatic labeling machine
- Automatic vial washing machine
- Chromatography columns
- Dehydrogenation oven
- Explosion proof refrigerated centrifuge
- Fermenter system including controls and automation
- High Pressure homogenizer
- High Pressure Liquid Chromatography System
- High Speed Centrifuges
- Homogenizer (Low pressure)
- Instrumentation like pH probe, DO2 probe, Mass Flow meter, Methanol sensor, pressure transmitters, temperature transmitters, etc.
- Isolators
- Lot printing machine
- Low Pressure Chromatography System
- Lyophilizer / Freeze Drier
- Mobile laminar flow cabinet

- A Rs 50 crore fund as Innovation Development Fund to enable research scientists at academic laboratories to develop scientific innovations from a concept to a form that is licensable. This fund should be under the administration of the Department of Biotechnology (DBT) and the grants may be capped at Rs 50 lakh per project.
- A Rs 200 crore Product Development Fund or Seed Capital Fund under DBT to enable Small and Medium Enterprises (SMEs) to develop in-licensed or in-house innovations to a "Proof of Concept" stage to qualify for VC funding. Such funds may be disbursed as 10-year soft loans with a two-year moratorium on capital repayment and a low interest rate of 3-5 percent. The loans may be capped at Rs 2 crore per project.

Duty exemption norms to include components: There exists a serious anomaly with respect to imported and indigenous diagnostics and life saving drugs wherein raw materials and components used by indigenous manufacturers for such products are levied customs import duty and excise duty whereas the finished products are allowed to be imported duty free. It is therefore recommended that components and raw materials used by indigenous manufacturers for the production of diagnostics and life saving drugs are exempt from Excise and Custom Duty.

Excise Duty waiver for diagnostic kits: Indigenous diagnostic kits are levied 16 percent Excise Duty whereas imported kits are exempt from all duties. Diagnostic kits are vital for HIV/AIDS, infectious diseases and other critical care applications. The positive impact of such an Excise Duty waiver will far exceed the small impact it will have on the exchequer.

Exemption on customs import duty on R&D equipment: If India is to realize the full potential of its scientific skill base at a commercial level, it is imperative to adopt all measures that reduce the capital cost of R&D. Currently, R&D equipment as specified in List 27A and List 28 of the Custom Notification No: 26/2003 dated 01.03.2003 by DSIR recognized Research Laboratories are exempt from Customs Duty. These equipment are essential to biotech and pharmaceutical research.

Duty drawback for R&D consumables: Likewise, the import of R&D consumables are subject to the full incidence of Import Duties at nearly 33 percent as no Countervailing duty credit is available on R&D consumables. It is therefore recommended that import of R&D consumables be made eligible for Duty Drawback based on DSIR certification.

Weighted average tax deduction on R&D expenditure: The current provision for a 150 percent weighted Tax deduction u/s 35 (2AB) for R&D expenditure incurred by DSIR recognized Research Laboratories has been a great boon to incremental R&D investment. With the new challenges imposed by the WTO-TRIPS regime, R&D investments will need to be augmented even further. It is therefore recommended that the weighted deduction be increased to 200 percent and the scheme be extended for a further period of three years i.e., up to 2010.

Inclusion of international patent filing costs u/s 35 (2AB): There exists a lacuna in the current taxation system wherein expenditure pertaining to Indian patent filings is eligible for weighted tax deduction but international patent filings are disallowed. Now that WTO-TRIPS has taken effect and given the increasing importance of international patents in exports to regulated markets, it is recommended that expenditure pertaining to international patent filings be included u/s 35 (2AB) for weighted tax deduction for R&D.

Exemption of withholding tax for technology transfer and licensing: The existing requirement for withholding tax for technology transfer results in increased cost of import of technology. In order for Indian companies to acquire technology, it is recommended that import of technology by the biotech sector be exempt from Withholding Tax for a period up to 2010.

Laboratory

- Air Sampler
- Anaerobiosis Jar
- Beta Counter
- Cell Roll
- Centrifuge
- Colony Counter
- Double Door Class 100 oven
- Electrophoresis System (DNA and protein)
- Filter Integrity Test Equipment
- Fireboy
- Flow Cytometer
- FPLC chromatography
- Gamma Counter
- Gas Chromatography system
- Glucose and Lactate Analyzer
- High precision analytical balances
- HPLC Chromatography
- Hybridization Oven
- Image Analysis System
- Inverted Optical Microscope
- Kjeldahl System
- Low temperature incubators (-20oC and below)
- Micro-centrifuge (microlitre)

Relaxed export obligation norms for biotech parks availing of SEZ status: The changes in Foreign Trade Policy permits biotech companies located in state sponsored biotech parks to avail Duty free import of equipment, instruments and consumables and tax holiday under Section 10A/10B of the Income Tax Act. However, the above benefits are only available to 100 percent Export Oriented Biotech Units and therefore similar to the benefits enjoyed by 100 percent EOUs in all other industrial sectors. It is also recommended that the Export Obligation norms be made applicable after a duration of five years.

Minimum requirement for a biotech SEZ: The minimum area required for setting up a Biotech SEZ be restricted to 25 acres of land or 1 million sft of building area, similar to the norms specified for the IT industry.

One-year moratorium from price control: Biotech products manufactured in India be given a one-year moratorium from price control under NPPA to provide for sufficient time to scale up production and streamline costs. The present requirement for approval from NPPA prior to launch leads to substantial delay in launch of the product. It is also recommended that R&D expenditure incurred on biotech products be permitted for amortization in computing costs for the purposes of price fixation.

Expansion of the list of capital goods under list 27A and 28: The concessions presently provided to biotech companies permitting duty free import of equipment as per List 27A and List 28 of Custom Notification No 26/2003 dated 01.03.2003, by manufacturers having a R&D wing registered with the DSIR, to the extent of 25 percent of the FOB value of exports made in the previous year is not beneficial as List 27A and List 28 covers R&D Equipment and as such they cannot be used for manufacture. Also new companies cannot avail of these benefits, as they would not have any exports in the previous year.

It is therefore recommended that the existing schemes be amended to cover the following:

- Expansion of the List of Equipment provided in List 27A and List 28 to cover equipment required for manufacture of Biotech products as per Annexure.
- New companies be permitted to import equipment at Nil Duty to the extent of 25 percent of the project cost, as certified by DBT or recognized financial institution. The restriction of 25 percent of FOB value of exports and recognition by DSIR be waived for new companies for a period of five years from date of incorporation.

Priority sector lending for biotechnology: Biotech entrepreneurs have great difficulty in obtaining bank financing as this sector has a high-risk profile with long gestational time lines, which are not conducive to lending. Currently, lending to the agri-business sector as well as to venture funds is categorized as Priority Sector Lending. It is therefore recommended that lending to the biotech sector be categorized as priority sector lending. Also it is proposed that Rs 200 crore of funds under the Technology Development Board be earmarked for providing long term funds to biotech companies

Budgetary allocation for state supported biotech parks: Though several state governments have taken initiatives to promote biotechnology parks, there is need for an incentive from the central government in form of budgetary allocation to support state governments in furthering the interests of biotechnology through dedicated parks. The parks can also facilitate development of incubation facilities, which would help entrepreneurs or start-ups with limited resources to carry on their innovation-related activities.

Budgetary allocation for an IPR arbitration council: With India's commitment to TRIPS agreement under WTO and introduction of Product Patent regime from January 1, 2005, it has become imperative to enforce the same with the same spirit. However given the stress under which Indian judicial system operates and backlog of cases, industry feels that existing system would not be capable to handle the IPR related disputes efficiently. Additionally, the judges may not be fully versed with the technical details of IPR related issues and there is need to have specially trained judicial personnel and courts to showcase India as next hub for contract research, clinical trials and contract manufacturing in biotechnology space.

Budgetary allocation for a world-class accreditation agency: India can leapfrog in biotech with quality manufacturing and services. This requires setting up of an internationally accepted accreditation agency, which can set standards, protocols and act as gatekeeper for producing world-quality products and services. The agency can also liaison with internationally bodies of repute such as USFDA, BP and TGA for setting up guidelines for its functioning and operations.