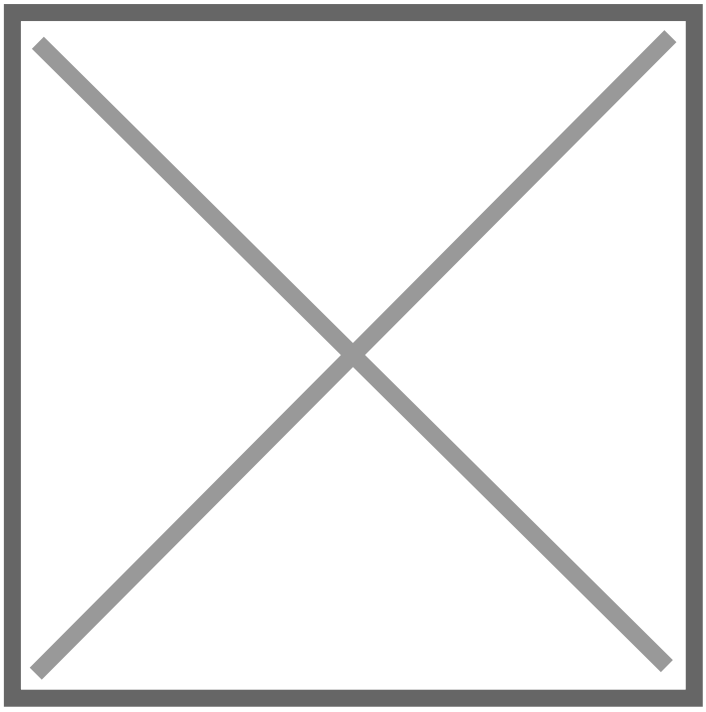


Biotechnology industry's demands to the FM

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With the annual budget session round the corner, the biotech industry is geared up with its list for Finance Minister Chidambaram. The various industry associations like ABLE, AIBA, CII and FICCI have taken the feedback from their member companies and submitted their demands to the finance ministry. We are presenting here the comprehensive list of what the industry needs from the finance minister based on the collective recommendations made by the four industry associations (ABLE, AIBA, CII and FICCI).

Duty exemption norms for imported life saving drugs and diagnostics to include components for indigenous manufacture of same

There exists a serious anomaly with respect to imported and indigenous life saving drugs and diagnostics and wherein raw materials and components used by indigenous manufacturers for such products are levied customs duty and excise duty whereas the finished products are allowed to be imported duty-free. This is detrimental to indigenous manufacturing and instead encourages trading. Furthermore, it puts indigenous manufacturers at an unfair disadvantage to MNC competition.

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 based on standard input/output norms certified by the Department of Biotechnology or alternatively duty paid on components and raw materials used in manufacture of life saving drugs be eligible for refund.

Exemption on customs import duty on R&D equipment

The biotechnology sector is capital intensive necessitating investment in expensive R&D infrastructure. Currently, R&D equipment as specified in List 27 A and List 28 (Custom Notification No: 26/2003 dated 01.03.2003 by DSIR recognized Research Laboratories) are exempt from customs duty. It is recommended that this list be expanded to cover some more additional essential equipment. In addition, due to the ever-changing requirement of new types of equipment, it is recommended that additional R&D equipment not covered in List 27A and List 28 be permitted to be imported duty free based on DSIR certification.

Further, though customs duty levied on items falling under List 28 attract Nil basic Custom duty but are liable for payment of additional custom duty of 16 percent, Educational Cess 2 percent, Cumulative Educational Cess 2 percent (some equipment are exempt under Not. 69/04) and Additional Duty of 4 percent which totals to 21.47 percent on the CIF value of the equipment imported. The purpose of exemption of basic duty to equipment for research is to promote investment in basic research but the same is being nullified by subjecting it to additional duty of 16 percent. Second, there is exemption against

the additional customs duty applicable to only Public Funded Research Organizations or Non Profit Research Organizations where they have to pay only five percent Custom Duty on Equipment for Research (under Not. No. 51/96). With a strong need to create equality, the customs duty exemption on capital goods and raw materials should be exempted to all biotechnology companies engaged in R&D, irrespective of the fact whether they are funded by the Government or private funded.

New companies should be permitted to import R&D equipment at nil duty to the extent of Rs 25 crore, as certified by the DBT. The restriction of recognition by DSIR for new companies should be waived for a period of five years from the date of incorporation.

Duty refund/drawback for R&D consumables

The import of R&D consumables, reference standards and reference books are subject to the full incidence of import duties as no countervailing duty credit is available on R&D consumables. To encourage more companies to set up research labs, it is recommended that import of R&D consumables, reference standards and reference books be made eligible for refund/duty drawback or duty credit based on DSIR certification.

The government may also consider providing relief to recognized biotech, pharmaceutical and clinical research companies by giving a blanket permission, of say up to Rs 1 crore per annum, for import of laboratory consumables, which can be certified as non-hazardous, if required.

Additional items to be included in the list of capital goods under List 27 A and List 28

List of equipment used in biotech industry

Production

Animal Cell Culture Fermenter

Automatic closing machine

Automatic filling machine

Automatic labeling machine

Automatic vial washing machine

Chromatography Columns

Depyrogenation oven

Explosion Proof Refrigerated Centrifuge

Fermenter System including controls and automation

High Pressure Homogeniser

HPLC

High Speed Centrifuges

Homogeniser (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

Lyophilliser / Freeze Drier

Mobile laminar flow cabinet

Refrigerated Centrifuges

Reverse Phase High Pressure Liquid Chromatography System

Revision tables

Sterile Cartridge filters

Tangential Flow Filtration System (including Microfiltration, Ultrafiltration, Diafiltration)

Tubular Centrifuge

Laboratory

Air Sampler

Tax holiday

The tax holiday scheme is nearing completion (10 year scheme expires on March 31, 2007) and 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. The weighted deduction be increased to 200 percent and the scheme be extended for a further period of eight years i.e. up to March 31, 2015 to encourage a greater plough back into R&D.

Alternatively, DSIR recognized Research Laboratories could be made eligible to deduct from Corporate Income Taxes an amount equivalent to 20 percent of Qualified Research Expenditure, similar to the practice followed in the US.

Further, it is important to note that the provisions for weighted deduction u/s 35 (2AB) does not cover agribiotech companies. Given the increasing importance of research on agribiotechnology, it is recommended that the expenditure pertaining to this segment be also included in the ambit. The weighted deduction under section 35(2AB) should be extended to investment made in land and buildings for dedicated research facilities.

Inclusion of international patent filing costs u/s 35(2AB)

The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology. In this context, filing of patents both in India and abroad is critical. The expenses for filing patents especially outside India are prohibitive and a major barrier to effective IP management in the country. Also whilst expenses incurred with filing of patents in India is eligible for weighted deduction, similar benefit is not provided for expenses incurred with regard to filing patents outside India. As IPR creation is a pre-requisite for exports to the regulated markets, it is recommended that expenditure incurred with regard to filing patents outside India be also eligible for weighted deduction U/S 35 (2AB).

Recognition of anti-cancer drugs as life saving drugs

The cost of cancer treatment in India is very high. Further, there are not many effective drugs available in the market. Anti-cancer drugs form a substantial cost of the treatment of cancer patients. The impact of customs duty at the rate of 12.5 percent, Excise/CVD at the rate of 16.32 percent, education cess at the rate of 2 percent and additional duty on Customs at the rate of 4 percent would result in a 36.74 percent increase in the price of the drugs, thereby increasing the cost of treatment substantially.

It is requested that an exemption from customs duty on the import of anti-cancer drug and from excise duty on the manufacture of the drug, be granted by including such anti-cancer drugs under List No. 4 of item 83 of the Customs notification No 21/ 2002, and under list 3 of item No 54 of the Excise tariff Notification No. 4/2006.

Exemption of withholding tax for technology transfer and licensing in biotech

For the Indian biotech sector to flourish it is important that Indian companies enter into collaborative research programs and import/license platform technologies thereby permitting Indian companies to expand their existing skill base and shorten timelines from research to commercialization. The existing requirement for withholding tax for technology transfer results in increased cost of import of technology. To facilitate Indian companies to acquire more technology, the import of technology by the biotech sector be exempt from Withholding Tax for a period up to 2010.

Excise duty on diagnostic kits for infectious diseases

Presently, diagnostic kits used for detection of HIV antibodies are exempt from customs duty under List 4 and CVD/CED under the Central Excise Act. It is recommended that diagnostic kits for other infectious diseases such as hepatitis C, malaria, tuberculosis, etc. also exempt from customs duty and CVD/CED as it falls with the category of life saving drugs.

Concessions to biotech companies located in biotech parks

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, these 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.

Since the biotech companies are in a nascent stage it is not possible for these companies to commit to export obligations. To facilitate the growth of the sector it is recommended that the requirement for export of products be waived and the

concessions be also extended to companies supplying Biotech products to the domestic sector.

Expansion of list of capital goods under List 27 A and 28

The existing schemes be amended to cover: Expansion of the List of Equipment provided in List 27A and List 28 to cover additional equipment required for manufacture of biotech products and new companies be permitted to import equipment at nil duty to the extent of 25 percent of the project cost, as certified by the DBT/Recognized Financial Institution. The restriction of 25 percent of FOB value of exports and recognition by DSIR should be waived for new companies for a period of 5 years from date of incorporation.

Inclusion of clinical trials as "technical testing or analysis services" under the Export of Service Rules, 2004

Expenditure incurred on clinical trials by companies is currently not accepted as an expense to be included for weighted tax deduction at the rate of 150 percent under section 35 (2AB) of Income Tax Act, 1961. It is submitted that the tax benefit should also be extended to expenditure incurred on clinical trials for all companies. Since expenditure incurred on scientific research is allowed; there is no reason why it cannot be extended to clinical trials as well.

Second, service tax was imposed on clinical trials for testing of drugs and formulations this year. Accordingly, fees charged for clinical trial services in India would now attract service tax at the rate of 12.24 percent (including education cess) under the category 'technical testing and analysis services' in the hands of the Indian Clinical Research Organization (CRO). Further, service tax would also to be liable on pass through costs of the Indian CRO (such as investigator fees, transportation etc). Thus the service tax would be an additional high impact cost to the nascent Indian clinical trial industry and a huge deterrent, especially at a stage where India is facing increased cost competitiveness from countries in Latin America, Easter Europe and China. It is therefore suggested that CRO industry be exempted from the levy of Service Tax on all its activities including clinical trials to encourage it.

Waiver of requirement of filing form ER-5 & ER-6 under Cenvat Credit Rules 2004

The present requirement of submission of detailed returns on input-output norms for each product requires biotech companies to reveal sensitive information about inputs used in the manufacture of biotech products. As this information is confidential and will reveal proprietary information it is recommended that biotech companies be exempt from this requirement.

Implementation of service tax rebate/refund notifications

Currently, exporters of taxable services by the biotech industry are eligible for rebate/refunds of service tax and cess paid on input services used in providing taxable service exported. However, although the applications for the above rebates/refunds are piling up with the department, so far, no rebates/refunds have been granted to the export service providers.

It is requested that the refund/rebate sanctioning authority be suitably instructed to adhere to the instructions contained in the circular 828/5/2006-CX, and grant the initial refunds/rebate within 15 days of filing the duly completed refund/rebate application. In general it is requested that the officers be instructed to process the refund/rebate claims within a reasonable period of time and to grant the refunds/rebates, on merits.

Two year moratorium on obtaining price approval for products under price control

It is recommended that biotech products manufactured in India be given a two-year moratorium from price control under NPPA (National Pharmaceutical Pricing Authority) 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.

Provision of a central fund of Rs 200 crore to compensate states that provide subsidy on approved transgenic seeds

The deployment and growth of Bt cotton seeds in the last three years has unequivocally demonstrated the benefits of transgenic technology in Indian Agriculture. The transgenic seeds today are priced at about 3-4 times the price of the non-transgenic counterpart, due to the investments in developing/in licensing the technology and the high regulatory costs prior to its commercialization. Though the high seed cost is more than compensated by the tangible benefits that the technology provides, it makes the technology unaffordable, at least in the initial years to the small and subsistence farmers of this country. Subsidizing the seed cost, at least partially, will go a long way in the penetration of the technology among small farmers, who incidentally will stand to gain the most from such technologies. Further, subsidy for the approved varieties of transgenic seeds will also effectively curb the menace of unapproved and fake transgenic seeds, which is rampant in the

country today.

Priority sector lending for biotech

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. Whilst agribiotech can avail of such lending, the rest of the sector which is as risk prone is unable to access such finance. It is therefore recommended that lending to the biotechnology sector be categorized as priority sector lending. This step will surely spur the biotech business in the country.

Budgetary allocation for setting up arbitration council or quasi judicial tribunals to address IPR disputes

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 setting up an internationally accepted accreditation agency

For India to take leap in the biotechnology space there is need to offer quality in both manufacturing as well as services domain. This requires setting up of an internationally accepted accreditation agency which can set standards, protocols and act as gatekeeper for producing world-quality products / services. The agency can also liaison with internationally bodies of repute such as USFDA, BP, TGA etc. for setting up guidelines for its functioning/operations.

Customs duty exemption on biopesticides

Industry also recommends that biopesticides and biocontrol agents should be exempted from levy of both the custom duty and excise duty in the next budget. Currently the excise duty rate being charged on them is 16 percent, which is the same as on hazardous chemicals. To promote the use of eco-friendly, non hazardous and biodegradable biopesticides the excise and custom duties should be withdrawn. In addition, the biopesticides and biocontrol agents should be exempted from levy of VAT (Value Added Tax).

Concessions in the capital gains tax for investors in dedicated biotech venture capital funds

In order to encourage setting up of dedicated biotech venture capital funds in the private sector, a modification in the current capital gains tax is needed. This will not only encourage investments by institutions into such venture funds but will also catalyze significant capital from high net worth individuals (HNIs) and pharmaceutical companies into the biotech sector. A capital gains tax of zero for investors in venture capital funds dedicated for investments in biotech companies is recommended. To qualify for this benefit such venture capital funds should be registered with SEBI.

Removal of current restriction for Foreign Direct Investments in biotech sector

Whilst pharma and most other companies are permitted 100 percent FDI under the automatic route, biotech companies manufacturing recombinant products require FIPB approval for any foreign direct investment (FDI). It is recommended that since there is a strong regulatory system in place evaluating/approving the manufacture of recombinant products, 100 percent FDI be also permitted in the biotech sector.

Clarification in excise tariff in consonance with HSN

It is requested that an appropriate note be incorporated in the Chapter 30 of Central Excise Tariff (CET) to avoid confusion/misinterpretation in regard to classification of "Diagnostic Kits" and remove the items "HIV Diagnostic Kits" and "Pregnancy Diagnostic Kits" from Chapter 38.22 of CET.

Technical expertise at airports

There is a lack of technical expertise at the airports and ports to handle the biological materials. Customs officials may be updated regularly with the new policies on issues related to handling of biological materials. The registry of chemicals / biochemical of the customs database at the ports /airports may
be updated.

Duty exemption for biofuel and ethanol production

Bio-fuels may be used as an alternative environmentally friendly fuel in the future. The government may consider extending tax incentives like excise and import duty exemption to promote use of bio-diesel and ethanol in auto fuels in order to slash India's oil dependence. It is proposed that the investments made by corporates on jatropha plantations, maize and soybean plantation for ethanol production should be given tax holiday for a period of 10 years from the beginning of the oil/ethanol production. In addition, there should be no import duty on machinery and equipments used for esterification of Jatropha oil and for ethanol production from maize and soybean.