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Invest more in innovation venture funds

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Association of Biotechnology Led Enterprises (ABLE) is a not-for-profit national forum that represents the Indian Biotechnology Sector. With more than 200 members from across India, ABLE catalyzes a symbiotic interface among the industry, government, academic and research institutes and domestic and international investors

1. **Innovation fund**

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Government of India (GOI) should invest more money in setting up venture funds especially to support all companies that support innovation in India, be it foreign-owned or locally-owned. It should also encourage innovation by providing seed funding to help indigenous biopharmaceutical companies license new technologies and intellectual property from other countries and build on them. Such funding can take the form of mixed grants and loans, with repayment of the loan element contingent on success. The existing funding programs provide support to the companies that have products in the late stage of development, but there is a crippling paucity of risk capital for early stage innovation. Moreover, assuming that such innovation will only be performed at academic institutes is too restrictive an approach. Start-up biotechnology companies can be effectively groomed to conduct directed research.

2. **Export tax incentives**

Export promotion in this sector should remain one of the top priorities. Tax incentives were available on exports made by STPs (Section 10B) till March 2011. These were withdrawn from assessment year 2012-13. To encourage exports in this sector considering the economic scenario, this tax benefit should be restored in the next Budget.

3. **Tax incentives for research activities**

3.1 As per the current tax incentives, 200 percent weighted deduction is available to those firms that are engaged in manufacturing or production. There is a sunset clause prescribed for availability of this incentive for expenditure incurred up to March 31, 2012. The uncertainty associated with outcome of research & development (R&D) makes it a challenging task, especially where investments are high and anticipated return is low. Investments in R&D may not always fetch a high return immediately. Withdrawing the benefit of 200 percent weighted deduction may prove to be a dampener to most industry players undertaking or proposing to undertake research & development in India. In order to provide an impetus to R&D growth, the benefits of the weighted deduction should be continued beyond March 31, 2012.

3.2 The rate of weighted deduction should be increased from a present rate of 200 percent to 300 percent, consideringthe long gestation period to break-even and R&D incentives offered by other countries.

3.3 The contract research organisations (CROs) are not included in this scheme. The CROs in India are increasingly focusing on leveraging their in house potential to do R&D. Hence to promote long-term growth of India as a R&D hub, this scheme should also be extended to include the CROs. Apart from this, there is also a need to introduce benefits in the form of research tax credits to promote India as an R&D hub.

3.4 Weighted deduction should be provided for certain activities like outsourced clinical trials and R&D, preparations of dossiers, foreign consulting or legal fees for new chemicals entities and abbreviated new drug applications filings with the US FDA patent defending charges. This would facilitate companies to outsource part of research activity for cost efficiencies.

3.5 Exemption of 100 percent profits of companies engaged in scientific R&D for a period of 10 consecutive assessment years should be extended for the companies obtaining approval till March 2013. Currently, this benefit is available only if company was approved by prescribed authority before April 1, 2007.

4. **Recommendations pertaining to minimal alternate tax (MAT) and service tax provisions**

4.1 Lot of sector specific special economic zones (SEZs) have come up and biotech SEZs are one of them. The SEZ benefit is almost removed by extending the coverage of MAT from April 1, 2012. By this the total tax benefit of SEZ is withdrawn. Weighted deduction (for R&D activities in case it is restored) should be allowed while computing the MAT liability as the current rate of MAT (18.5percent) remains very high.

The SEZ and biotech units are huge capital assets oriented, and normally they have depreciation benefit for the initial period of five to 10 years.

Applicability of this section practically makes the companies claiming tax incentives (under Section, 80-IC, etc) as a tax payer. Keeping this in mind these companies should be exempted from MAT that facilitates them to continue to retain their cost advantage and thereby help gain higher share in the global research business.

Especially, last year, the finance minister left companies in SEZs grumbling as they were brought within the minimum alternate tax net. This has made SEZ investment unattractive. The upcoming Budget should abolish MAT on such companies.

Service tax provisions

4.2 Service tax on any activity directly or indirectly relating to clinical trials as well as R&D should be exempted.

5. **Conversion to Limited Liability Partnership**

5.1 Limited Liability Partnership (LLP) promises to be an excellent form of business organization as it provides manifold benefits in the form of minimal legal and procedural requirements to operate, tax benefits and simplicity in setting up, maintenance and wind-up, to name a few.

5.2 Presently, conversion of a company into an LLP is exempted from capital gains tax, provided the totals sales turnover or gross receipts in the business of the company in any of the three previous years preceding the previous year in which the conversion takes place does not exceed Rs 60 lakh . Given the importance of the LLP model and the thrust of the government to promote the same, prescribing such a small limit of up to 60 lakh would certainly be a great deterrent for large pharma companies proposing to move to an LLP mode. Hence, this condition of limit of Rs 60 lakh needs to be removed.

6. **Section 115A â€“ Royalty and fees for technical service payments**

6.1 Indian companies are required to make royalty and fees for technical services payment to non-residents. Currently

Section 115A provides for a concessional rate of tax for income in respect of royalty or FTS received by a foreign company from an Indian concern and where the agreement between the foreign company and the Indian concern is in accordance with the industrial policy. There is ambiguity in the term â€œin accordance with the industrial policyâ€?. Clarification is needed in the ensuing Budget that payments permitted by Reserve Bank of India under the Current Exchange Control Regulations should be regarded as covered within the industrial policy.

7. **Mergers and acquisitions**

7.1 In the current economic environment that the world is going through, restructuring of business (merger, de-mergers, acquisitions) plays an important role. In this context, following amendments should be brought about in the upcoming Budget:

- There are stringent conditions prescribed for availing the benefit of carry forward and set-off of loss amalgamating company to the amalgamated company. The same does not remain relevant in current scenario and accordingly the same should be modified.

- The benefit of carry forward and set-off of loss is currently restricted to specified business. The same should be extended to all sectors, especially service sector, which currently cannot avail the benefits.

8. **Section 206AA â€“ Withholding tax compliance**

8.1 The implementation of Section 206AA has resulted in additional compliance burden and also increase in cash outflow for Indian players in net of tax situations where the tax on such payments is borne by them merely because the non-resident has not furnished his PAN. To avoid undue hardship to such Indian players, this clause should be removed in the coming Budget.

9. **Extension of 100 percent tax-free status for biotech and pharma SEZs**

9.1 This status for biotech SEZs should be increased from five to 10 years because of the regulatory gestation.

10. **Transfer pricing issue**

10.1 Transfer pricing issue relating to the comparison between companies engaged in clinical trial support services with CRO companies needs to be addressed. An Indian company that provides a low-end clinical trial related support services should not be compared with full-fledged CROs for transfer pricing purposes. Safe harbor mark-up percentage should be prescribed for contract research and development services.

11. **Other recommendations:**

11.1 **Agriculture sector:** With growing population, the country faces an immediate challenge in food security. The productivity in the agriculture sector has not increased to meet the growing demands on food production. Agri-biotechnology provides immense opportunity to meet the existing challenges in this sector. Further reforms in agricultural education, including making the farmers and the general public understand the new developments in agri-biotechnology as well as appreciate immense potential of this sector, is urgently needed. Funds of a total 100 crore should be allotted for the educational reforms as well as general dissemination of the strengths and weaknesses of modern agri-biotechnology.

11.2 Duty exemption norms is required for raw materials imported for indigenous manufacture of life saving drugs and diagnostics. 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 be exempted from excise and customs duty based on standard input or output norms certified by the Department of Biotechnology or alternatively duty paid on components and raw materials used in manufacturing of life-saving drugs be eligible for refund.

11.3 **Recognition of anti-cancer drugs as life-saving drugs:** The cost of cancer treatment in India is very high. Newer anti-cancer drugs like monoclonal antibodies are increasingly being used to treat various forms of aggressive cancers like lung, breast, bladder, esophagus and stomach, head & neck, prostate and ovarian. Anti-cancer drugs

form a substantial cost of the treatment of cancer patients. The impact of customs duty at the rate of 10 percent, excise/ CVD at 10.3 percent, education cess at two percent, secondary and higher education cess at one percent and additional duty on customs at four percent would result in a 26.85 percent increase in the price of the drugs, thereby increasing the cost of treatment substantially.

Anti-cancer drugs are life-saving drugs and it is imperative that they are exempted of all taxes and duties. It is requested that an exemption from customs duty on the import of anti-cancer drugs and from excise duty on the manufacture of the drug, be granted, by including such anti-cancer drugs under List 4 of Item 83 of the customs notification No 21/2002 dated March 1, 2002, and under List 3 of Item No 54 of the excise tariff notification No. 4/2006, dated March 1, 2006.

11.4 **Duty exemption on diagnostic kits for infectious diseases:** Diagnostic kits used for detection of HIV antibodies and for detection of hepatitis B antigen are exempted from customs duty under List 4 of Item 83 of the Customs Notification 21/2002 dated March 1, 2001. It is recommended that diagnostic kits for other infectious diseases, such as hepatitis C, malaria and tuberculosis, are also exempted from customs duty. Further, List 3 of Item no 47 and 55 of the Excise Notification No 4/2006 dated March 1, 2006, exempts diagnostic kits specified in lists 3 and 4 and also diagnostic kits for all types of hepatitis from excise duty as it falls within the category of life-saving drugs. It is recommended that diagnostic kits for other infectious diseases be exempted from excise duty.

11.5 **Excise duty exemption on molecular diagnostics for critical infections:** Critical infections are defined as those which result in death or loss of function in a patient within 96 hours after the onset of illness. Examples are brain and eye infections and septicemia where blindness or paralysis or loss of life will occur quickly. As of now, only molecular diagnostics such as polymerase chain reaction (PCR) and DNA microchips can provide answers for quick and accurate diagnosis. Since the patent on PCR has now expired there is a scope of making many generic PCR-based diagnostics in India and also export them, apart from development of some revolutionary diagnostics. However, these are excisable items and abolishing the duty will give price advantage for exports and the price relief for the Indian patients.

11.6 **Establish biotechnology finishing schools and exchange programs for biotechnology:** Like any other knowledge-based industry, the biotech industry also requires â€œindustry readyâ€? workforce. ABLE recommends that the government should implement the concept of â€œbiotechnology finishing schoolsâ€? in nationally important departments across India.

Emphasis should be given on â€œhands-on-trainingâ€? to students in industrially relevant areas, including work experience in GLP and GMP laboratories.

Further emphasis should also be given to data analysis courses as well as to the development of communication skills, both written and verbal. The ongoing pilot experiment in Karnataka with these finishing schools suggests that a fund of ₹100 crore may be required to initiate such a scheme at the national level.

Other recommendations include the following:

VAT/CST

- The levy of CST hampers free trade between states. We would like to propose a reduction in the CST rate from two percent to one percent in the Budget for FY 2011-12.

- It has been observed that the procedure for obtaining CST declarations in most states is very cumbersome. On behalf of the Indian industry, we would like to propose simplified procedures for obtaining CST declarations.

Excise duty

- Rate of central excise duty on pharmaceuticals formulations be continued at four percent.

- The generic excise duty rate on the inputs (active pharmaceutical ingredients or APIs) presently is 10.3 percent, whereas the generic excise duty rate on finished formulations is 4.12 percent. Traditionally, in the pharma industry, the excise duty rate on inputs has always been higher than the excise duty rate applicable to the finished products. This has led to an accumulation of Cenvat Credit in the books of the manufacturer, with the inability to utilize it efficiently. It is thus expected that the government either align the excise duty rates of APIs with that of the finished formulations or provide for a refund mechanism for the underutilized Cenvat Credit.

- All excisable goods used for R&D purposes to be exempted from excise duty.

- Increase in rate of abatement on medicaments from current 35 percent to 45 percent-to-50 percent to cover

the trade margins and the value of R&D costs and other costs associated with the pharma industry such as distribution of many medicines through cold chain (for example, vaccines).

Customs duty

- Presently, different medical devices have partial exemption under various entries in different notifications. Classification of different medical devices to bring more clarity or reduce dispute from classification aspect should be rationalized.

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