BioSpectrum the business of Bio & Health Sciences

Allocate funds for cGMP facilities

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Vaccine Manufacturers Association (VMA) brings together India's top vaccine producers Bharat Biotech, Biological E, Panacea Biotech, Serum Institute and Veterinary Biological and Research Institute, Hyderabad, on one platform. The following are the recommendations of the VMA:

A. Allocation of funds for the following activities and programs under the Ministry of Health and Family Welfare, Government of India:
   - For strengthening of Universal Immunization Programme to ensure proper coverage of all the target population of infants, children, pregnant mothers, for higher percentage of immunization.
   - For the introduction of adult vaccines in rural areas and among the urban poor.
   - For imparting intensive training to a higher number of vaccine administrators in order to reduce adverse events while administering vaccines and to assist in timely reporting of adverse events.
   - For the promotion of neglected vaccines such as vaccine against typhoid fever.
   - For supporting studies on the enumeration and estimation of the disease burden of infectious and communicable diseases in India.
   - For strengthening of the Central Drugs Laboratory (CDL), Kasauli, and establishment of the CDL in Hyderabad for South India.
   - To gather accurate consolidated data on the number of units manufacturing vaccines and other biotech products and for listing the products.

B. Allocation of funds on soft loan basis to the vaccine industry for continued maintenance of cGMP at their facilities and

for expansion of capacities. Huge proportion of vaccines are supplied to the Government of India and to the states at lower rates and the industry finds it difficult to purchase new equipment as replacements.

C. Allocation of funds to the Department of Biotechnology, Department of Science and Industrial Research under the Ministry of Science and Technology:
    - For extending funds for discovery of new molecules in biologics.
    - For funding clinical trials of vaccines in other developing countries by vaccine manufacturers.
    - For establishing training centers to train workforce for vaccine and biotech production and testing.
    - For release of funds to the departments to assist vaccine manufacturers to attend international conferences organized by selected organizations.
D. Special reduction in excise duty, sales tax and value added tax for vaccines that are, in general, given to infants, children and mothers for the prevention of specific infectious diseases and, therefore, for better health. Vaccines, in fact, are life- saving interventions.

Research and development incentive provisions
SECTION 35 (2AB)- Scientific research: Issue of concern

- Increase the quantum to encourage more participation since the incentives are inadequate for risky investment coupled with long gestation periods involving complex business environ
- Recognizing Limited Liability Partnership as an entity eligible
- The existing provisions of the Income-tax Act allow weighted deduction of expenditure incurred for R&D activities. To provide further boost, the weighted deduction in case of in-house R&D expenditure incurred by companies engaged in the business manufacture and production of articles and things. The weighted deduction should be increased to 250 percent from the existing 200 percent.
- Weighted deduction is available for companies engaged in manufacture and production of articles and things or engaged in biotechnology. The deduction was introduced to enhance indigenous research. This was given further impetus by increasing the deduction to 200 percent. However, the deduction is expiring by March 31, 2012. Extension of this provision beyond March 31, 2012, is suggested. Further, the contribution based deductions for R&D should also be increased as under:
    - In order to facilitate holistic and pervasive development of R&D activity in the country, it is imperative to promote innovation not only in pharmaceutical, auto or agriculture industries through benefit of enhanced deduction on account of R&D but also cover other equally important industries like information technology, biotechnology, among others.
    - Clinical trial expenditure is aimed to secure confirmation about the suitability and efficacy of a proposed drug on a particular set of living beings. The clinical testing is under regulatory mechanism of the Drugs and Cosmetics Act. As per this Act, a clinical trial is required to be undertaken only by organizations approved under the Drugs and Cosmetics Act.

An in-house research is not permissible under Drugs and Cosmetics Act.

Sec 35(2AB) of the Income Tax Act, stipulates to provide relief of weighted deduction, if and only when expenditure is incurred on in-house research, while the regulatory law does not permit in house research mechanism for clinical trials. The scientific research is incomplete and does not get recognition unless clinical trials are concluded as per regulatory requirement under Drugs and Cosmetics Act.

Thus, the stipulation under the Income Tax Act, 1961, fails to recognize certain key element of scientific researchexpenditure for granting weighted deduction purely for reasons that it is not in-house. We recommend a suitable provision for recognizing clinical trials as part of scientific research for weighted deduction.

The recommended areas for granting weighted deduction in respect expenditure which are at present ignored for consideration, under pretext that it is not an in-house expenditure are:

- Expenditure on clinical drug trial, carried under a recognized entity by the Drugs and Cosmetics Act
- Expenditure training approval from any regulatory authority under any central, state or provincial Act and filing an application for a patent.

Pharmaceutical companies claim clinical trial expenditure as eligible for weighted deduction for these reasons:

- Clinical trial expenditure is incurred as an extension to the in-house research of the company.
- Clinical trial expenditure is incurred on in-house research and the tax law stipulates that the expenditure be incurred in in-house research of a company and hence expenditure incurred on in-house research is eligible.

However, tax authorities interpret that the clinical trial must be conducted in-house to claim the expenditure as eligible for weighted deduction. Clarificatory amendment is sought specifying that clinical trial expenditure incurred in relation to the drugs developed by the company should be eligible for weighted deduction irrespective of the fact whether clinical trial is undertaken in-house or is outsourced.