

Industry needs easy access to R&D; products

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With a commitment and zeal to nurture the fledging clinical trials industry, the industry in India can prosper and flourish only if it can maintain its global cost advantage. However, with service tax as an additional cost, the Indian clinical trials industry may just end up losing all that it has gained so far and bring to naught its future growth potential. Hence, there is a need for exemption of service tax and duty-free import of live animals like mice and rats by 100% EOU for research activities.

Evaluation of the effect of compound in animal models of human diseases is important before safety of the compound is established in two species of animals—rat/mice and dog/monkey. It is mandatory to establish the safety and efficacy of experimental drug candidates in animals prior to clinical trials in humans. Until alternative validated approaches that are acceptable to regulatory authorities become available, industry has little choice but to continue with animal testing. Delays sometimes in procurement or use of animal models arising from stringent procedures or policies may delay the pre-clinical development of a potential drug candidate.

Among other issues, procurement of plasmid cDNA clones of human origin is essential for target-based drug discovery. The plasmid cDNA clones are propagated in a harmless strain of *Escherichia coli* (*E coli*) and no toxins or toxic subunits are produced. The cDNA clones are non-mutagenic, non-toxic, non-contagious and non-hazardous. In addition, they are free from viruses, not pathogenic, and pose no risk of transmission or infection and are essential for the discovery of novel therapeutics for diseases such as cancer and diabetes. R&D; work with such clones help in drug discovery, which is in-turn licensed to multinational companies, gives us earnings in foreign currencies.

There is a need for advance permission for customs clearance of imported perishable materials. Most of the research materials imported for biotechnological R&D; are perishable in nature with a very short shelf life, which need to be stored in minus 80 degree centigrade temperature. Delay in clearance of these materials would contaminate the material and renders it useless and need to be re-imported thereby increasing forex outflow. Suggestions are made that goods of perishable nature used in drug discovery/R&D; may be allowed for customs clearance on priority.

It is also seen that most of the 100% EOU do not collect service tax from their clients, whereas they are made liable to pay service tax for availing all the input services. Suggestions are made that 100% EOUs be exempted from payment of service tax.

There should also be exemption from local sales tax (VAT) for purchase of research related consumables. Lastly, expenditure incurred on clinical trials by companies is currently not accepted as an expense to be included for weighted tax deduction at 150% under section 35 (2AB) of Income Tax Act, 1961. It is recommended that the tax benefits should also be extended to expenditure incurred on clinical trails for all companies. The industry is concerned with 37% duty on instruments, which makes R&D; more expensive.

—The writer is CMD, Bharat Biotech International Ltd.