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Leading associations urge government to ease norms, relook at certain regulations

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Leading associations urge govt to ease norms, relook at certain regulations



Requesting the government to consider keeping clinical trials services out of the ambit of service tax, the the Association of Biotechnology Led Enterprises (ABLE) Â has said that 12.36 percent tax mentioned in recent budget, would increase the cost of drug development in India and lead to a corresponding increase in the price of the tested drugs.

As per ABLE, the drug development in India is already facing challenges on several fronts following which the number of global and local clinical trials has come down substantially. The decreased number of trials will impact availability of drugs in the medium to long term and will increase dependence of Indian patients on imported drugs. ABLE has urged for keeping these services out of the service tax for another five years.

The CDSCO (Central Drug Standard Organization), on Jul 28, had invited suggestions on its notification for improving its clinical trials management through application of information technology. Calling it a laudable step, ABLE and Association of Contract Research Organizations (ACRO) India have, however, cautioned the DCGI (Drug Controller of India) to preserve confidentiality of the patients. The industry body has also requested to retain the existing CRTI website for clear visibility of clinical trials in the country.

Says Dr P M Murali, president- Association of Biotechnology Led Enterprises (ABLE), "India's pharma & biotech industry has the potential to generate combined revenues of more than $100 billion by 2025 from approx. $ 25 billion as of today. To realise this quantum of growth, the right policy framework needs to be put in place. The sector must be provided with incentives through a number of tax-friendly measures to make it globally competitive."

As per Mr D A Prasanna, chairman - Association of Contract Research Organisations (ACRO) India, "While it is a good move to implement IT enabled system for clinical trials, the proposed guidelines are not in favour of protecting patient privacy. It is critical not to discourage the participation in clinical trials. Hence the guidelines need to be more specific as to how the personal details would be kept confidential for the reassurance of all stakeholders involved."

Various concerns are already affecting the quality of skilled labour as several companies have moved their clinical trials outside the country. It is imperative to set up a quick, time-bound, fact-supported mechanism that uses scientific methods and reasoning to resolve issues. As per the Industry Associations, clinical trials represent an example wherein all stakeholders can and should work together with a common goal of making the whole clinical research process safe and transparent.