BioSpectrum
the business of Bio & Health Sciences

Indian CROs have an edge over Chinese

09 April 2007 | News

Image not found or type unknown

Indian CROs have an edge over Chinese

Finance Minister P Chidambaram has proposed the exemption of service tax for clinical research organizations (CROs) in the recent Budget. And this move is expected to add strength to the existing advantages India offers to the sponsors.

The Indian clinical research organizations (CROs) sector is growing at nearly 70 percent over the previous year's revenues of Rs 425 crore with exports dominating the sector. There are over 70 companies active in this space. Most of these are actively involved in doing bioavailability/bioequivalence (BA/BE) studies with a handful of them into clinical trials (Phase Iâ€“IV).

Considering the potential of doing business in India, many leading CROs of the world who are looking at both India and China as potential markets of investments, are entering India. Given the two countries' low cost base and huge potential patient populations, both the countries are offering services in abundance.

According to a report on "Looking Eastward" from the Boston Consulting Group, almost all the top multinational pharmaceutical companies have already offshored some clinical trial work to India and many have offshored to China as well. The surge has been extraordinary. Considering the advantages India has and its offerings to the sponsors, McKinsey has estimated that the size of the clinical research market in India will be close to $1.5 billion by 2010. At present the market is just $160 million. But will the ambitious $1.5 billion number become a reality? The government has been making all efforts to make this dream come true. Some of the issues concerning the CROs have been addressed in the Union Budget 2007 like doing away with the service taxes.

At the cost of losses

Service tax was imposed on clinical trials for testing of drugs and formulations last year. Accordingly, fees charged for clinical trial services in India had attracted 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 CROs.

Further, service tax would also to be liable on pass through costs of the Indian CROs (such as investigator fees, transportation etc).

It may thus be seen that service tax would be an additional high impact cost to the nascent Indian clinical trials industry and a huge deterrent, especially at a stage where India is facing increased cost competitiveness from countries in Latin America, Eastern Europe and China.

The main reason till date for the growth of the clinical trials industry has been India's superior cost arbitrage, which has negated factors such as infrastructure challenges and the fact that India is not 'near shore' vis-Ã -vis the global players. For instance for the fees charged, if the US has a price base of 100, India and China run neck to neck with a price base of around 66, with the Latin American countries following closely at 75 and Eastern Europe at 80. Accordingly, China and Latin American countries are extremely close to India in terms of "price for clinical trials".

In such a scenario, Indian CROs would completely lose out on their price/cost advantage and international competitiveness if service tax at 12.24 percent is added to their fees charged as well as the pass through costs. It is therefore suggested that the CRO industry be exempted from the levy of service tax on all its activities including clinical trials to encourage it. Since it is a nascent industry as also to enable to retain its internationally competitiveness.

Post the recent Budget announcements, Indian CROs are on a high, as now the testing and analysis service provided by the CROs in relation to testing and analysis of newly developed drugs on human participants to ascertain the safety and efficacy of such drugs is fully exempted from levy of service tax with effect from March 1, 2007. This will result in an estimated revenue loss of Rs 50 crore for a full year to the government.

Welcoming the initiative, Dr Kiran Marthak, director, Veeda Clinical Research, Ahmedabad, said, "The government has recommended waiver of service tax of 12.5 percent for the new drugs that will include new chemical entities, new formulation, new mode of admin and sustained release/extended release formulation etc. Thus it will not only help in conducting various phases of clinical trials but will also aid bioequivalence clinical trial study for newly developed formulation for better compliance."

Dr Arun Bhatt, president, ClinInvent Research, New Delhi, said, "The removal of service tax on clinical research will allow us to give competitive pricing to our sponsors. This will also save valuable time and efforts of our project and finance team, which has been earlier lost in explaining to our foreign clients the concept of service tax and in complying with the requirements of filing returns."

Sharing his thoughts, Prashant Tewari, managing director, USV Ltd, Mumbai, said, "Clinical research is being encouraged as part of the budget provisions and is also expected to gain momentum due to the impetus provided." Similar views were echoed by Vimal Kumar, whole time director, Shasun Chemicals & Drugs Ltd, Chennai. He said, "The move to exempt service tax on clinical trials and the cut in duty for pharma research equipment will be beneficial for the overall safety and efficacy trials in the industry."

Dr Surinder Kher, CEO, Jubilant Clinsys, New Delhi, said, "Certainly this is a positive step. This notification will translate into the Indian companies offering a 12.36 percent saving to the sponsors of clinical studies. Any saving is definitely an advantage but decision-making on outsourcing, besides being based on the cost advantage is also based on a few other factors which are equally critical like the quality of work, the confidence of working in a particular geographic territory, knowledge of English language among others. So this step will give a positive impetus to the industry but at the same time, I do not see this decision having an immediate impact on the volume of studies coming to India, especially from the US or UK."

Reacting to the Budget proposals, Dr Rajeev Soni, COO, Premas Biotech, New Delhi, said, "These will certainly provide the boost to Indian CRO industry and will lead to a huge expansion in not too distant future. The only question and/or concern is that is this benefit extended to contract research organizations as well."

He added, "The budget proposals would give a leading edge to Indian CROs in terms of cost competitiveness, bagging more projects in the global market. And it might help to a certain extent for next five years or so as the costs of operating in India are going up. Ultimately, it will be quality combined with cost rather than cost alone that will attract global giants towards India. The move by the finance minister will certainly benefit the sector and more companies would start operations in this area thereby inducing competitiveness."

"Exemption from service tax of companies involved in clinical trials or NCE development work, reflects the growing incentivization of basic R&D. The point to note is that there are few companies involved in clinical trials. The way forward to meet the objectives of boosting R&D would be to extend the benefits across the spectrum of clinical trials," said Utkarsh Palnitkar, leader, business advisory services, Ernst & Young Pvt Ltd, Hyderabad.

Voicing his views, Dr Shivprakash, managing director, Synchron Research Services, Ahmedabad, said, "The finance minister has provided the much needed cost advantage to our international and domestic clients to make India a favorable destination for clinical trials. The finance minister must also look into the possibility of bringing the CRO industry on par with the IT industry in terms of tax structure, which will help CROs build international standard R&D facilities for clients."

"CROs spend quite a sum on rent. This is high in case of CROs with BA/BE. Service tax on rent affects adversely. Removal of service tax benefits sponsors and improves cost position for India. Changes in ESOP make it expensive to reward and retain top quality professionals," said DA Prasanna, managing director, Manipal AcuNova, Bangalore.

Nitin Deshmukh, private equity group, Kotak Mahindra Bank Ltd, said, "Service tax exemption for the companies engaged in drug testing and clinical trials of drugs is a positive outcome of this Budget. I am however very disappointed with ESOPs being brought under FBT. This will be very adverse for the development of biotech industry in India. ESOPs are an integral part of the growth process of any biotech company as well as the industry. Unlike IT, the biotech industry is highly capital intensive, high risk and not cash flow positive or enjoys low profitability for long initial years. While the IT industry is probably mature in the Indian context, the biotech industry is yet to take any critical mass by global standards. Therefore ESOPs under the ambit of FBT is very damaging for the biotech industry. This measure has probably being taken with focus on the more profitable IT industry without understanding the collateral damage to other fledgling sectors such as biotech.

"As such India as well as China are considered the preferred economic countries for conduct of clinical trials. With the waiver of service tax, India will attract more clinical trial activities as it would now become cheaper by 12.5 percent and will also help Indian pharma R&D companies in exploring various phases of clinical trials within the country. On the whole, the waiver of service tax will bring more customers to contract research organizations, said Dr Kiran Marthak.

The government cannot fulfil all needs of the industry at a time. But it can take up the issues one after the other. The government is keen support the sector so that it can compete in the global market.

Narayan Kulkarni with inputs from Rolly Dureha & Namratha Jagtap