

## Budget disappoints India biotech industry

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The 200 percentage weighted tax deduction by companies on research and development (R&D) expenses will continue till March 31, 2017. However, the biotech industry's demand to extend these provisions to outsourced R&D and clinical trial expenses have not been accepted

Budget in the decade dedicated to innovation, the biotech industry, which relies heavily on innovation, is not on top of the Government of India's priorities listed in the Union Budget for 2012-13.

The only saving grace in the budget presented in Parliament on March 16 is that the 200 percentage weighted tax deduction by companies on research and development (R&D) expenses will continue till March 31, 2017. However, the biotech industry's demand to extend these provisions to outsourced R&D and clinical trial expenses have not been accepted.

These two are key components of innovative drug discovery and the industry is disappointed by the government's neglect of this activity.

In fact, while the budget has talked about reducing import duty on some life-saving medicines, vaccines, for which the Indian industry is acclaimed the world over, will become costlier. The budget has proposed doubling of excise duty on finished vaccines, from one to two percent, and further slapped duties on imported raw materials. Then there is additional service tax on many aspects of the business. However, import duty on some key medical equipment and stents have been reduced by half to 2.5 percent.

- Five-year extension of 200 percent weighted tax deduction on R&D expenses
- Setting up of 50 billion India Opportunities Venture Fund with SIDBI for MSME
- Import duty on some key medical equipment and stents reduced by half to 2.5 percent
- Excise duty on finished vaccines increased from one to two percent
- 100 percent coverage for National Immunization Programme
- Hike in excise duty on raw materials from 10 percent to 12 percent
- Allocation of 200 crore for development of new technologies for seeds and plants
- Agri universities in Orissa, Haryana, Karnataka, Kerala and Andhra Pradesh to get a combined bonanza of 350 crore
- Weighted deduction of 150 percent on expenditure incurred for agri-extension services
- Outlay for Rashtriya Krishi Vikas Yojana that covers animal healthcare sector increased from 7,860 crore to 9,217 crore
- Plan to set up integrated vaccine unit at Chennai

Yet, the Finance Minister has proclaimed that in the wake of successful elimination of polio due to vaccination in the country, the national immunization program will target 100 per cent coverage. Currently, vaccination coverage hovers around 76 per cent for essential vaccines.

The budget has tried to increase modern seed production, but not specifically the transgenic seed varieties. The good news on this front is that premier agricultural research centers, the Kerala Agriculture University, Trichur, and the University of Agricultural Sciences at Dharwad, Karnataka, will get 100 crore and 50 crore, respectively, as special grant to boost research. Few other agricultural universities in Orissa, Haryana and Andhra Pradesh will get a combined bonanza of 200 crore in the budget.

Small biotech companies could look forward to raising some capital from the new stock exchange for small and medium enterprises. The budget has allocated 5,000 crore to help the exchange through the funding organization, Small Industries Development Bank of India.

The Association of Biotechnology Led Enterprises (ABLE), a national forum that represents \$4 billion biotechnology industry in India, while welcoming some of the measures, said it is disappointed that there was no major announcement to spur innovation and growth of the biotech sector, at a time when the government has declared this as the 'Decade of Innovation'.

On the agriculture front, ABLE is happy to note the allocation of 200 crore for the development of new technologies for seeds and plants and a grant of 350 crore to agriculture universities across the country, which will ensure that the benefits of technology in agriculture reach the citizens of the country.

### Reactions: Budget 2012

The industry was largely disappointed with the provisions of the budget.

Ms Kiran Mazumdar-Shaw, CMD, Biocon, said, "I expected nothing out of this Union Budget, and the Finance Minister has certainly met my expectations." According to her, the government's proposal to tax foreign shareholding with retrospective effect is a "highly retrogressive step that will have serious implications on India's economy and business".

"Instead of using this budget to proclaim that India is open to business, the government is closing the doors. It appears to be the administration is agenda. Their objective is to raise revenues from any source possible. This is one rollback the government must effect immediately," she added.

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CMD, Biocon

She, however, had a word of praise on the extension of 200 percent weighted deduction on R&D. "I am pleased that the Finance Minister has extended by five years the 200 percent weighted deduction on R&D. The formulation of special guidelines to allow small and medium-sized enterprises (SMEs) to list on stock exchanges can help biotech start-ups get

Mr Nitin Deshmukh, member, executive council of ABLE, and CEO, Kotak Private Equity, said, "The 5000-crore allocated to SIDBI for Micro, Small and Medium Enterprises (MSMEs) is a very welcome step and many

small biotech companies will benefit from this."

He added that the reduction of customs duty from five percent to 2.5 percent on medical devices and CVDs, such as stents

and valves, and customs duty reduction on vaccines, life-saving and anti-cancer drugs are also welcome measures.

According to Dr Krathish Bopanna, president & executive director, Semler Research Centre, the budget proposes a number of regressive, retrograde and extraterritorial provisions that would significantly increase tax and alter the dynamics of cross-border transactions and M&As. It raises a question as to whether foreign investments are protected in India at all and whether it will give rise to claims under bilateral investment protection treaties, he said, adding that indirect taxes, service costs and excise duty would hurt the industry in a big way.

Mr Supreet Deshpande, CEO, VLife Sciences Technologies, comments that this is one of the most uninspiring budgets. Unsure strategies for curbing inflation and revenue generation ways are likely to harm all - consumers, industry and services. I wonder if it is really worth attaching so much importance to the budget after seeing this budget? No bold step, only political compulsions written all over, leading us nowhere, he said. According to him the biggest flaw is that the spending is scattered and not likely to give any decisive improvement in any single area.

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Mr Deshpande also pointed out that the industry gets no incentive to produce more but customers have to pay more due to increase in excise. As a result of the increase in price, if consumption drops by two percent, even the government will get nothing more. Same is the case with the services sector, he says. With an increase of two percent of service tax, the only gainer is the government, he remarked, adding nothing for my sector, except continuation of 200 percent deduction on R&D

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Dr Shama Bhat, chairman & managing director, Bhat Bio-tech India, too found the budget a total disappointment and said there is nothing in it to encourage the industry, particularly the biotech industry. The increase in excise duty will be a total disappointment. Already, we have a very high tax system, which puts our products at a cost disadvantage against other countries such as China, said Dr Bhat.

He, however, has a word of praise too. Setting up of the India Opportunities Fund is good and will help new entrepreneurs, he says, while pointing out that the much-awaited relief on raw materials import for the diagnostic industry still did not materialize.

Mr Pawan Chaudhary, chairman & managing director (CMD), Venus Remedies remarked that most of the pharmaceutical companies have their subsidiaries or arms overseas and are subject to international tax.

The positive stance shown by the Finance Minister on Advance Pricing Mechanism is encouraging and would certainly help the industry. Pharma sector is also facing a challenge in having talented manpower. Additional incentive announced on account of weighted deduction on skill development will go a long way in helping the sector, he said, while pointing out that increase in both excise duty and service tax would result in additional burden.

Dr Ajaykumar Sharma, practice head in Pharma, Healthcare Practice, Frost & Sullivan, South Asia & Middle East, said there are two aspects to the budget. One is for the rural populace, which seems to have been positively benefited from the budget. However, for the second, urban populace, there has hardly been any impact. For the industry as a whole, the budget seems to be in line with their expectation of increase in service and excise tax structure.

Mr Apurva Shah, chairman of Association of Clinical Research Organization (ACRO) India, found Budget 2012 a halfhearted effort to promote R&D. Commenting on the government's proposal to extend weighted deduction of 200 percent for R&D expenditure, he said, We had expected the government to recognize that CROs account for an important component of R&D and, therefore, the R&D set off should be spread to cover R&D done outside pharma companies in CROs. By doing so, it would speed up the R&D process and position India as a leader in pharmaceutical R&D.

Mr Shah praised the fund set aside for training and hoped that these funds can be availed to train professionals to conduct ethical clinical research as per Good Clinical Practice.

Some provisions in the agriculture sector received a thumbs up from Mr D Narain, India Region Lead in Monsanto. The budget proposals for 2012-13 are positive and progressive and they should help generate farmer-led inclusive growth in the agriculture sector. The provision of a weighted deduction of 150 percent on expenditure incurred for agri-extension services will facilitate growth in the sector. With this all stakeholders engaged in extension of research will be encouraged to invest in the upgradation of cultivation or agricultural practices for improved returns to the farmers. Similarly, an increased allocation of funds to state agricultural universities will enhance the level of research currently underway, he said.

Mr Narain further said given the challenge of water scarcity, the focus on micro-irrigation and drip irrigation schemes with allocation of ₹14,242 crore is a big step forward and, if implemented well, it will give a fillip to the yield and increase farm incomes. "While we are hopeful that the measures announced by the Finance Minister will give much needed boost to the agricultural sector, concerted efforts will be required towards sustained policy support, economic incentives and clear regulatory framework to achieve the desired growth rate in agriculture and make Indian agriculture globally competitive," he added.

Mr K V Balasubramaniam, MD, Indian Immunologicals, said he was disappointed that there was no relief granted as weighted deduction for outsourced R&D and clinical trials or lower duty on R&D and testing equipment.

"On the other hand, with excise on finished vaccines increased from one to two percent and without the Cenvat setoffs, hike in excise duty on raw materials from 10 to 12 percent (similar impact on imports from higher CVD), and the service tax hike, our input costs will rise. This will squeeze our already thin margins," said Mr Balasubramaniam. "However, with better outlays for health, especially for achieving the targeted 100 percent vaccination coverage, as the Finance Minister said in his speech, and also higher outlays for the Rashtriya Kisan Vikas Yojana, which covers the animal health sector, we expect better business opportunities for our human and animal vaccines."

Dr Rajesh Jain, joint managing director, Panacea Biotec, terming Budget 2012-13 as a balanced budget. "It is not very encouraging as far as the pharma sector is concerned. The government's plan to set up an integrated vaccine unit at Chennai in south India will affect the private players in vaccine industry. A two percent increase in basic excise duty rate from 10 percent and service tax increase from 10 to 12 percent will affect profitability. There is no mention about the weighted tax deduction on clinical trials outside approved R&D center, tax exemption on pediatric medicines and tax exemption on new hospitals," he said.

Sharing the same views, Dr Vinay Konaje, founder and director, Navya Biologicals, said, "Overall, budget is balanced, keeping in mind the hostile political environment, with focus on infrastructure development. As for its impact on an R&D company like Navya, there is no impact of the budget, either positive or negative, on our operations. Not specifying an early time line for implementation of Goods and Services Tax (GST) is a negative."

Sharing his thoughts, Mr Rajen Padukone, CEO, Manipal Hospitals, pointed out that the Prime Minister's promise to increase spend on public health to reach 2.5 percent of GDP in the next five years does not reflect in the budget. To reach that number, expenditure should more than double in five years whereas the budget provides only 15 percent increase.

Mr Daara Patel, secretary-general, Indian Drug Manufacturers' Association, said the Union Budget was not very exciting for the pharma industry. "We are afraid that it is going to be difficult for the companies to maintain the price line as excise duty on bulk drugs has gone up from 10 to 12 percent and for formulations, from five to six percent. Also, increase in service tax from 10 to 12 percent is further going to affect the cost of medicines," he said.

Terming the budget as another bitter pill for the life sciences industry, Mr Hitesh Sharma, National Leader & Tax Expert - Life Sciences, Ernst & Young, said, "Contrary to the expectations of the industry, there is no major incentive or reform for life sciences industry. For an industry already reeling under pricing controls and competition, general increase in service tax and excise duty from 10 to 12 percent is likely to increase both input and output costs further. A five-year extension for 200 percent weighted deduction for in-house R&D, increased deduction to 150 percent of capital expenditure incurred for hospitals and deduction of ₹5,000 for preventive health check-up are positives for the industry, but with limited impact. List of drugs and medical devices eligible for lower import duty and excise duty exemption expanded to include additional life science drugs."

"While a slew of amendments in transfer pricing and international tax side likely to impact companies across the board, including pharmaceutical companies, introduction of Advance Pricing Agreements (APAs) is a welcome move," added Mr Rahul Patni, associate director, Life Sciences, Ernst & Young.

On the policy side, Mr Hitesh Sharma said, "The government has continued its focus on augmenting healthcare infrastructure and spends for masses by increasing allocation to various healthcare schemes, including the National Rural Health Mission (NRHM), by approximately 15 percent."

Managing Director of Advanced Enzyme Technologies, Mr C L Rathi, said he did not see any visionary movement in budget. "Biotechnology is not much on government agenda. The last state elections have their mark on the current government."

Mr Krishna Prasad, managing director, Granules India, commented that the budget was in line with expectations, given the current political atmosphere. "The government missed an opportunity to improve the country's fiscal health by not

reducing subsidies. Instead of directing new revenue into programs that offer short-term benefits and hurt the country over the long-term, it would have been prudent to hold on to the revenue to demonstrate the government is serious about reducing fiscal deficit or at the very least, invest in capital expenditures, which will benefit the country and ultimately improve growth rate," he said.

According to Dr Kiran Mazumdar-Shaw of Biocon, with this Budget, the government had an opportunity to take decisive strides in the direction of socio-economic progress, "but sadly it remains inert. It is time to remember that actions speak louder than rhetoric", he said.