

Budget '09 The Countdown begins

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Over the years, the Finance Minister has been giving life sciences due emphasis in his budget decisions. As the industry awaits Finance Minister P Chidambaram's last budget before the general elections kicks start in early 2009, industry stalwarts give their wish list to the minister.

The overall Union Budget 2008 has clearly reinforced the strong image that India will attain on the world economic stage. But at the same time, the Manmohan Singh government's budget proposal 2008, sent out one clear message that life sciences as an industry can certainly not be ignored primarily due to the mammoth growth opportunities that it brings along with it and the significant investments happening both by domestic companies and MNCs in the sector.

Budget over the years

Budget 2006

1. Corpus for the R&D fund to be increased in phases. Stable policy environment and incentives to be provided to help the two industries (biotech and pharma) become world leaders.
2. Units in knowledge-based industries such as pharma and biotech to be provided equity support through the SME Growth Fund.
3. The exemption date for weighted deduction of 150% of in-house R&D facilities of pharmaceutical and biotechnology companies has been extended by 2 years to March 31, 2007.
4. Also, the exemption for 100% deduction of profits of companies carrying on scientific R&D, which is approved by the Department of Scientific and Industrial Research has also been extended by 2 years to March 31, 2007.
5. Customs duty for 9 specified pharma and biotechnology machinery cut to 5%.
6. Corporate tax pruned to 30% from 35%.

Budget 2007

1. Reduction of customs duty on 10 anti-AIDS and 14 anti-cancer drugs to 5%.
2. Reduction of duty on certain life saving drugs, kits and equipment from 15% to 5%. These drugs will also be exempt from excise duty and countervailing duty (CVD).
3. Expenses on free samples of medicines and medical equipment distributed to doctors exempt from fringe benefit tax.

Budget 2008

1. Reduction in excise duty on all pharmaceuticals from 16 per cent to 8 per cent as well as total exemption from excise duty for the anti AIDS drug, Atazanavir.
2. Increase in budget allocation for polio elimination program (Rs10.42bn) and for AIDS control program (Rs9.93bn) which could be positive for companies like Panacea, Matrix, Ranbaxy, Cipla.
3. Further allocation for the health sector has been increased by 15% to Rs165.3bn.
4. Certain specified life saving drugs and their bulk drugs customs duty has been reduced to 5% from 10% as well as total exemption of excise duty.
5. Weighted deduction of 125 per cent on any payment made to companies engaged in research and development for promoting outsourcing.
6. Grant of five year tax holiday to encourage hospitals to be set up anywhere in India, except certain notified areas in tier-2 and tier-3 towns (for period April 1, 2008 to March 31, 2013).

Industry Wish list

The past year has seen a lot of events unfolding in the Indian life sciences industry-a spree of acquisitions, the prominent one

being the Ranbaxy-Daiichi Sankyo deal leading to the forging of stronger Indo-Japanese relations; MNCs setting shop in the country and even India Inc going overseas and etching a name for themselves on foreign land. Given this scenario a lot of budget expectations are soaring high on the eve of 2009 budget announcements. The UPA's Budget 2008 might have been lauded by industry stalwarts but there have been unfulfilled expectations which the industry hopes will be addressed this year. BioSpectrum has been able to put together the recommendations and suggestions from different sectors of the life sciences industry as the government makes an early start to its election year budget planning

CRO

"We would like the same exemptions from service tax on generic research as New Drug research. The generic drugs are the drugs used by the masses and will benefit general population so should be encouraged. Moreover the Indian drug companies are doing this research for selling the drugs in the international market so it brings in export revenues. The CROs should get the same benefits of taxation and customs as in-house R&D units in pharma cos. Such as customs relief on lab equipment and IT benefits under section 80IA.

-Apurva Shah and Binoy Gardi, Co-Founders and Co-Group Managing Directors, Veeda Clinical Research

I would like to see the government recognize clinical research as industry separate from biotechnology.

-Sampath Kumar, Founder and CEO, Sristek

BioSuppliers

All the imported consumables which are not used as commercial end product but are only used in R&D should not attract any custom duty

The transaction from bonded warehouse should be more flexible, like one page single document should be sufficient from customer to get the goods cleared from the warehouse and should be valid for six months in place of bunch of papers for each transaction even for \$ 100.

India is lacking in terms of high precision capital equipment manufacturing used in drug discovery / molecular biology / biochemistry R & D and hence government should come forward and shake hands with private industries to manufacture the same here.

Products for malaria and syphilis detection should attract no Import Duty and must be treated as critical products in line with HIV, HBV, HCV. Malaria and syphilis tests are mandatory to be carried out on each unit of blood donated.

Abolition of the Excise duty from the Laboratory Chemicals since these products are used in the analytical labs and for the research purpose. Elimination of the ED shall help in reducing the cost structure for the scientists and shall boost the R & D activity.

The MRP on the labels of laboratory reagents should be eliminated: This was initiated at the beginning of the current financial year, since these products reach the consumers (who are part of the industry and research institutions) directly at discounted rates hence the MRP does not hold much value.

The legal procedures for getting all the desired licenses mandatory for the laboratory solutions business for e.g. Solvent Storage license should be made as simplified as possible so that attaining the same and adhering to them is easier.

-Sushil Mehta, MD, RFCL

To better the supply time and to reduce hassle in order processing, it would be good to bring the custom duty for the dealer import and end customer import to same level. Currently DSIR labs, Government institutes and pharma get special customs duty due to which they import product directly from the manufacturer abroad instead of buying locally in local currency. Especially the Government institutes spend lot of time in tenders, comparing different currencies and different payment terms, freight cost. Lot of valuable scientific time is spent on order processing. If the customs duty is brought to similar level all offers will be in Indian Rupees and it is easy to compare as well as get product immediately from the dealer stock. Also, the dealer can import in bulk and pass on the benefit to the customer.

A lot of companies are interested in doing assembling in the country to take advantage of the growing business. If parts are bought on CKD basis and assembled in India special custom duty should be considered. This point is connected to the point one, since the customer pay less duty for direct import from countries like Germany they tend not to buy the assembled product.

- *Sankaranarayan, MD, Eppendorf India*

In the absence of any mandatory regulatory framework like compulsory accreditation of clinical testing laboratories, labs in India look at following quality practices as a "Cost". Until the government comes up with policy statement on this issue it is prudent to encourage labs to follow internationally accepted Quality control practices by making them available at lower prices. Reducing the customs duty from the current 31.74% to Nil (as is done in the case of Elisa products to promote HIV testing) will go a long way in achieving this objective.

Lesser duties for the life science research products like consumable and instrument should be passed on all the labs engaged in the R&D activities in the country.

- *Dhiren Wagle, Country Manager, Bio-Rad*

Biofuel

The recent biofuel policy declared by the Government of India has been well supported to the industry particularly in the down stream side. However, to achieve the 20 per cent blending mandate, the following points needs to be addressed.

- It should be addressed as to how the various Government Ministries like Rural Development and Panchayat Raj will work towards achieving this objective of planting 35 million acres under bio diesel plantations. NREGA scheme (routed through the Rural Development Ministry) can be utilized to promote the bio fuel plantations across the country. Many of the villages have common land and waste lands which can be put under bio fuel plantations under the NREGA scheme. The harvest from bio fuel plantations will provide a source of revenue for the panchayats later.
- Yields from bio diesel crops are obtained from the third year onwards. Most of the farmers are not willing to invest their money on bio diesel plantations because of this gestation period. Hence banks and insurance companies should play an active role in providing finance and crop insurance to farmers and entrepreneurs undertaking bio diesel plantations.
- The Government should also provide subsidy to farmers undertaking bio diesel plantation. A single agency with offices in every state should be made in charge of this subsidy. Farmers should receive subsidy for bio fuel plantation in reasonable time and with minimum effort.
- To bring in 35 million acres under bio diesel plantations, planting material to the tune of 3500 million to 35,000 million is required depending on the crop chosen. A certifying agency to certify the variety of the planting material needs to be established failing which fly by night operators selling poor quality planting material will be active.
- The 10 year bio fuel target has to be broken down into shorter phase wise targets from 5 % to 20 %. The short term targets will make the various other stake holders like vehicle manufacturers, procurement companies, logistics companies, oil expelling units and others to gradually prepare themselves.
- The Minimum Support Price (MSP) per kilogram of the feedstock (Jatropha seed, Pongamia seed) should not be more than 20 % of the price of diesel. If feedstock prices are greater than 20 %, bio diesel production becomes unviable. Ex: If the current price of diesel is Rs 30/ liter, the price of Jatropha or Pongamia seeds should not be more than Rs 6/ Kg.
- Finally government should release the list of bio diesel crops which can be planted by the farmers and

be eligible for various subsidies. Government should also try to promote bio diesel plants native to each region.

- Some State Bio fuel Boards are active while some are inactive. Each of these Bio Fuel Boards have different mandates and different focus. The National Bio Fuel Coordination Committee and State Bio Fuel boards should work towards a common objective.

All these suggestions will help India to reduce dependence on crude oil, provide employment in rural areas, rural industrialization, additional source of income for various stakeholders including farmers and self sustaining without any oil subsidy from the government.

- C S Jadhav, Director Marketing, Nandan Biomatrix

Medical Equipment Manufacturer

The government needs to recognize medical technology as an industry, which is reeling under unprecedented tax burden (36 per cent). There was no special mention made for the industry and no reduction in custom duties for the import of medical equipments/devices in the previous year's budget. The government has not given any incentives like capital grants and subsidies for local manufacturing of medical devices as well.

The Finance Minister has proposed to increase its healthcare allocation by 21.9 per cent and has extended a 5 year tax holiday for setting up hospitals in non-urban cities, but this however will not reduce the cost of healthcare in the country, until the cost of medical equipments are reduced. Health of the common man has been neglected and so has been the government's attitude to the Indian medical equipment manufacturer.

- Dr. G S K Velu, Managing Director, Trivitron Group of Companies, India & Overseas

Pharma

As far as incentivizing R&D initiatives are concerned, the government has allowed weighted deduction of 125 per cent on any payment made to companies engaged in Research & Development, to promote outsourcing of research. However, no additional fiscal incentives had been proposed for R&D activities. Since discovery research is lengthy and expensive, OPPI recommends that present R&D incentives should continue till 2017.

- Tapan Ray, Director General, Organization of Pharmaceutical Producers of India

All the budget allocations are vanity if the government does not act. One of the greatest challenges the Government faces is its ability to see that this benefit really reaches the people to whom it is meant for, and that these projects get implemented within the framework of budget and time. According to a recent review by the government, 301 planned projects were delayed up to 96 months with the cumulative cost over run of more than Rs 48,000 crore. This urgently calls for better governance and active involvement of all the ministries involved in health, education and infrastructure.

- Habil Khorakiwala, Chairman, Wockhardt

We hope the FM pays heed to the long standing request of industry to do away with FBT on physician samples and also tones down the penalties on transfer pricing adjustments. A major disappointment was the lack of investments in infrastructure. The economic engine cannot continue to grow at 9 per cent if no investments are made in this sector and this was notably missing.

- Ranjit Shahani, President Bombay Chamber of Commerce & Industry (BCCI) and Vice Chairman & Managing Director, Novartis India

Biotech/Biopharma

There is an absence of industry ready scientific research workforce, which is one of the major constraints in the growth of biotech sector in India in spite of large number of graduates and postgraduates who are academically qualified. Innovation based smaller companies or start-ups cannot invest in training and even a service oriented biotech cannot wait for the training, as capable hands are required at short notices. An initiative like Institutes of Biotechnology on the lines of IITs, focused on practically ready workforce could have been a step in this direction. Provision for initiatives with longer lasting impact like these, seem relatively less.

- Supreet Deshpande, Founder & CEO, VLife Sciences Technologies Pvt Ltd

Effect of the global meltdown / Current economy crisis

It might have been an action packed year for the life sciences industry. But the year 2008 will also be remembered for a sudden spurt of economic turmoils in the form of an 11.7 per cent inflation shooting up oil prices in particular, then global meltdown which had its rippling effects even in Indian shores. Fear now looms as to whether India should be prepared for a recession. However is the life science industry effected in any ways and will that in any way effect the budget proposals 2009. Back in life sciences, there is an apprehension that the Government can cut down in R&D expenditure.

Said a well known figure in the of a pharma company and who did not wish to be quoted, "The ones mainly effected would be companies heavily invested in R&D and that too for companies outside India and who will now have to face increased cost pressure now." A sneak peek whether or not life sciences has been affected:

CROs on the whole are not affected by the global turmoil. This sector is not really affected by mainstream economic market dynamics. In fact now, pharma companies in the US, which are now facing hurdles of high cost pressures will outsource all the more. They will outsource their clinical research work to these CROs which will lead to a further boost in their business. Yes, I do agree that share prices have been impacted but it is not that drastic for CROs.

- *Anurag Sharma, William Blair International Limited, London, UK*

With regards to the current global financial crisis, I think generally there is going to be a slow down, even though the impact on CRO industry will be lesser than other industries. The critical factor in all this will be how the banking industry shapes up. As long as Governments all across the world ensure that banks function normally and continue to lend to businesses, we will be able to recover sooner than expected"

- *Sampath Kumar, Founder and CEO, Sristek*

Currently we are not seeing any major signs of cut in R&D expenditure from government funded labs even though there is a global economic meltdown. The main thing affecting the scientific instrument industry is the currency conversion rate. The US dollar and Euro have appreciated vis-À-vis the rupee by approx 20-25 per cent in the past 4 months. This is forcing scientists to either postpone their purchases or compromise on instrument specifications to fit their purchases within budget.

The inflation and rise in fuel prices has increased business expenditure on travel, supply chain, across the board for all industry. This is resulting in increased pressures on margins for the scientific instrument industry.

- *Dhiren Wagle, Country Manager, Bio-Rad*

The budget proposals of the last few years clearly shows that there has been a significant decline in the customs duties in recent years. India has spontaneously deducted customs duties without having been influenced by foreign sources.

However, the industry leaders are very apprehensive about further decrease pertaining to custom duties because it is exceedingly being felt that chances of further deduction is a rare possibility in the forthcoming budget considering the impact of inflation and the global meltdown. Also, as the next general elections should be completed before May 2009. Hence the budget session of Parliament this year is not expected to present any new things in the budget. Upadhye, MD, LabIndia says, "I do not think if anybody will consider our requests this time. Parliament might just pass the routine expenses to be carried out till the new government takes over."

Therefore it is important that this Union Budget looks into the implementation aspects, maintains the projects that are already launched and thus makes the life sciences and healthcare delivery more efficient.

Jahanara Parveen with inputs from Nayantara Som & Shalini Gupta