HIGH HOPES FROM UNION BUDGET 2012-13

Like last year, this year's budget wish list seems overshadowed by the depreciation of the rupee, uncertainty on Goods and Service Tax and much more. But the pharmaceutical industry still expects a lot from Union Budget 2012-13. **Usha Sharma** rounds up the views of some industry veterans

'The Government should discontinue tax on voluntary free medicines'

The capability of the Indian pharmaceutical companies in providing affordable quality medicines is recognised globally. Also, India has emerged as a hub for collaborative and outsourced research and development (R&D). Further, there is a fundamental shift in the business model of Indian pharma companies from business driven research to research driven business.

Daara B Patel
Secretary-General
Indian Drug Manufacturers' Association (IDMA)

Considering the long-term benefits of R&D to the economy at large, all excisable goods used for R&D purposes, should be exempted from Central Excise Duty besides import of all capital goods, raw materials, consumables. Even reference standards for R&D purposes must be fully exempted from customs duty and other related duties. This will definitely boost our R&D activities significantly.

Goods and Services Tax (GST) will be implemented this year and we expect the total tax rate for the Indian pharma industry to increase. To ensure continued availability of medicines, the Government must uniformly exempt all life saving drugs from GST. In order to promote and support growth in Small Scale Industries (SSI), a higher threshold limit of ₹ 10 crore should be kept for SSI units under GST.

To ensure proper distribution and availability of medicines all across the country, the two per cent Central Sales Tax (CST) on Inter State Transfers should be discontinued to reduce transaction costs. Also, the benefits granted to units set up in tax free zones should be continued under GST. With the notification of Point of Taxation Rules, 2011, the term 'Service' needs to be very clearly defined for the purpose of Service Tax (ST) so as to exclude transactions, which are subjected to sales tax / Value-Added Tax (VAT) and related taxes and thus avoid duplication of taxes or provide clear exemptions in the ST provisions.

Non-profit organisations operating on a mutuality basis and regulated by applicable statutes (in particular bodies like Trade Associations & Co-operatives) need to be kept out of Point of Taxation Rules. Exemption limit for small service providers should be increased from ₹ 10 lakh to ₹ 25 lakh and should be in line with SSI Exemption Scheme under Central Excise. The eligibility limit of turnover of the preceeding years should be kept at a higher limit vis-a-vis the exemption limit, which may be around ₹ 75 lakh. We expect that as provided for business auxiliary services, exemption will be granted with regards to packaging services carried out on job work basis with regards to units, which are discharging Excise Duty at the final stage. Also, in line with the government's policy for other services, an abatement of 60 – 70 per cent may be granted with regards to manpower recruitment and supply service, with suitable revenue safeguards.

We expect that all contracts, which involve goods and service elements, would be brought under works contract service to provide parity of taxation and to avoid double taxation under both VAT and ST. Alternatively, benefit of composition scheme should be made available to all work contracts classified as such under VAT laws irrespective of its classification under the ST law.

As for Excise Duty at present, the rate of API needs to be rationalised and reduced from 10 per cent to five per cent, so as to be at par with other pharma goods. Abatement needs to be immediately increased to 45 per cent as the current 35 per cent abatement is not sufficient to cover the trade margins etc., and the value of R&D costs and other costs incurred by the pharma industry.

Also, a weighted deduction, twice the expenditure on scientific research incurred by a company is allowed. With increasing volume of exports all over the world, our companies need to invest substantial amounts in registration of products overseas. Hence, expenditure eligible for weighted deduction should also include expenditure on product registration in foreign countries and consultants' fees for patent / product registration overseas. At present, the weighted deduction is not available towards land and building.

However, for carrying out modern-day research, pharma companies need state-of-the art facilities. Several leading companies carry out research work at locations exclusively designated for this purpose. This requires infusion of huge funds on purchase of land and on construction of buildings specially designed for research. Therefore, it is imperative that such companies are also granted the weighted deduction on the expenditure incurred on land and building since such expenditure constitutes a significant amount of the total amount spent on research and development.

Also, pharma companies having their own approved R&D facilities and have to get bioequivalence study through outside agencies before they launch their products in the market. Since these expenses are an integral part of the R&D activity, they should also be made eligible for the weighted deduction even though they are incurred outside R&D facilities.

The Indian pharma industry has always responded to the urgent calls made by the Government, both at the Centre, as well as in the state level, during disasters and natural calamities by providing free medicines anywhere within the country, without keeping in mind about the production costs and expenses involved, in order to distribute the medicines to those who are affected. It is sad that despite our repeated requests and representations, the Government continues to tax these voluntary free medicines by imposing ED and ST on them. Considering the noble gesture by the pharma companies, Exemption Notification should be granted suo moto, with regards to medicines, which are supplied free of cost during calamities and where, Central Excise Duty has been paid in such cases, refund of duties should be promptly granted.

Pharma manufacturers are required to keep aside a few boxes of each batch of medicines manufactured till its expiry, as 'control samples' as per the provisions of the Drug & Cosmetic Act & Rules. These cannot be sold and as such should be fully exempted from Central Excise Duty. SME exporters incur expenses like US FDA audit and NSF. As in many other Asian countries, these SMEs must be allowed to take reimbursement from the Government for US FDA and NSF expenses so as to become globally competitive in quality and assurance. The basic customs duty on formulations should be rationalised and reduced to five per cent. Also, import of Reference Standards should be totally exempted from Customs Duty, CVD etc. Unlike last year, when our Finance Minister, Pranab Mukherjee, had almost overlooked the pharma industry, this year we expect that suitable incentives and concessions will be provided to keep our growth momentum going.

'Spend incurred by pharma companies on R&D will be a welcome move'

With the draft report still not tabled in the Winter Session both the Direct Taxes Code (DTC) and GST

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seems to miss its deadline this year. Implementing the two reforms in a haphazard way without having a proper discussion will be detrimental to the industry's R&D. The need of the hour is to support innovation. Any support in providing weighted deduction on the spend incurred by pharma companies on R&D will be a welcome move. With Indian generics proving itself to the world already, it would be really nice to see the first innovator drug being introduced by brand India in the next five years. In order to support this dream, the Government really needs to increase funding to R&D units and allow weighted deduction to pharma companies to boost more investments in this sector. Talking about Excise Duty, it should be rolled back to four per cent or at least maintained at the current level of five per cent on drugs and pharma.

regulatory approvals in India remains an obstacle in the eyes of sponsors. Unless the Government takes proactive steps, the sector may lose its shine. Contract research outsourced to India fetches foreign exchange, generates employment and encourages growing pool of various grades of scientists. It cannot be simply left to 'market forces'.

I expect this Budget to focus on meeting three key objectives:

1. Strongly promote scientific and research infrastructure development

2. Provide a huge thrust to R&D activities including clinical research

3.Provide improved access to healthcare and medicine for the consumer

In this regard, the first part should be addressed by giving the healthcare sector an infrastructure status with zero duty on R&D equipment and a longer tax-free allowance on pharma and biotech SEZs. Also, the Minimum Alternate Tax (MAT) that was increased from 18 to 18.5 per cent during last year's budget and included units falling within an SEZ needs to be reversed. Further, there should be an extension of tax exemption beyond FY 11 to pharma Export Oriented Units (EOUs).

India has yet to claim a blockbuster drug. Unless there is a research culture within the country, this will not happen automatically. R&D and clinical research activities should be incentivised by providing a five-year tax holiday on all products developed in-house, extension of weighted deduction on R&D on all research related services (currently in-house R&D at 200 per cent), grants and scholarships for translational medicine.

'Special incentives and grants as a package for encouraging women to be techno-entrepreneurs'

With the Sensex on a roller coaster ride and depreciating rupee value, insecurities have surfaced again in the industry. It is now a challenge for India to exploit the adversities to its advantage. Macro-economics will continue to encourage outsourcing in Contract

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Research and Manufacturing Sector (CRAMS). Within the CRAMS, the manufacturing sector is positioned better than the Clinical Research Organisation (CRO) sector. For the CROs, the much talked about 'India Advantage' since 2006 is getting eclipsed. Competition from China, ASEAN countries and the Middle East cannot be ignored. Time for

Further, impetus needs to be given to the promising biotech sector.

Currently life sciences companies engaged in R&D activities do not get any tax deductions, if the R&D lab is not approved by DSIR even though the company spends considerable money on such R&D activities. Hence, there is a need to bring in a provision of giving tax exemptions to companies doing R&D outside the purview of DSIR. A flat 10 per cent income tax on gross profit for the first five years will be welcome step for CROs to start-up. The incentives normally given to service sector that brings in foreign exchange need to be introduced / re-introduced for CROs. In order to make healthcare and medicines more accessible to the end-consumer, the government needs to take several measures including making all imported life-saving drugs more affordable to patients by eliminating the import duty, reverse the five per cent ST on diagnostic and testing services incorporated in last year's budget, remove the levy of one per cent Excise Duty on vaccines, intravenous fluids and medicaments (levy applicable where there is no Central Value Added Tax scheme being availed) and provide ST on exemption of central Excise Duty on physician samples.

Last but not the least, as president and founding chair for 'Women in Bio', India Chapter, I seek an announcement for special incentives and grants as a package for encouraging women to be techno-entrepreneurs, especially within the life sciences domain. I think it is time for India to venture and assert herself in the life sciences domain and the government needs to take some corresponding bold steps in this budget to address these.

'Certainty on Indian transfer pricing matters'

The Indian pharma industry has witnessed steady growth over the past years and is heralded as one of the sectors to drive the Indian growth story. Recognising the same, Department of Pharmaceuticals has also prepared 'Pharma Vision 2020' to make India one of the leading destinations for end-to-

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end drug discovery and innovation. The uncertainty surrounding the Europe and the US economy is raising questions on whether the Indian and Chinese economies will remain insulated from such global cues.

Budget being around the corner, the focus is back on whether the Government can support the pharma industry and propel the sector upwards. The Indian pharma industry to become a leader of tomorrow, will also need to be perceived as an innovator exhibiting wide range of R&D capabilities and new products development. The key ingredients, which could fuel the growth story could be increasing the scope of tax incentives for R&D expenditure, providing tax incentives for outsourced manufacturing activities and reduction in litigation and administrative burden amongst others.

The Budget can provide a new drug delivery system for such dosage by extending weighted deduction for R&D activity beyond 2012, giving incentives for core R&D activity players as well as incentives for expenditure incurred overseas, reducing litigation and administrative burden of establishing bona fides of expenditure, incentivise operations in rural areas, create harmony between various regulatory and tax authorities and certainty on Indian transfer pricing matters.

There is an urgent need for the tax authorities to provide transfer pricing rules and regulations. Some of the key aspects that need immediate examination would be (i) providing rules permitting the tax authorities to enter into advance pricing agreements with the taxpayers; (ii) providing a formal guidance for application of the comparable uncontrolled price method whereby, the innovator should be differentiated and not compared with the generics, except where such a comparison is based on a scientifically proven method/ guidelines. Even in such cases, cognizance should be given to the research and development spends by companies; and (iii) framing a policy to provide a benchmark of marketing spends by the companies, besides benchmarking of advertisement, marketing and promotional expenses, which are routine in nature and for expenses, which are of a niche/ non routine nature to prevent arbitrary adjustments on such expenditure.

Pharma manufacturers have made substantial investments in area - based exemption schemes, which had a Sunset Clause of March 31, 2010. The Central Board of Excise and Customs has issued clarifications regarding continued exemption to existing industrial units but codifying the same in the legislation, which will mitigate litigation on this count. Further, the tax rate of Value Added Tax and the list of tax-exempt goods should ideally be uniform across all states to avoid any dichotomy. Thus on a finishing note, the reform is needed both at a policy and tax incentive level for augmenting the industry, making the pharma industry more competitive at a global level, promotion of investment and smoothening of procedural issues. There is still a lot that government can do to boost this industry and help it reach its potential. However, with the Government's aim of phasing out the existing taxation laws in the country and bringing in the Direct Tax Code and GST, it would be interesting to see whether the Finance Minister gives these points due consideration.

'Important to curb inflation and higher investment slabs for individuals for tax exemptions'

I accelerate my wishlist from the upcoming budget. There should be a clear cut road map and GST – DTC should be implemented, considering huge losses due to weakening of rupee.

Some subsidy measures should be in place to ensure sustainability of SSI units. Clinical expenses being major and important cost on the R&D, it need to be covered for the purpose of allowing weighted deduction even if the clinical research works are done on an out-

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sourced manner. Dividend distribution tax should be reduced. There should be duty cuts and rebates on petroleum / oil / gases, which will help to curb inflation. Higher investment slabs should be in place for individuals for tax exemptions.

'Indian talent will require funds to start new ventures'

The idea is to invest in infrastructure for the biotech industry. Angel and

Dr PM Murali
Managing Director and CEO
Evolva Biotech

venture investors should be encouraged to invest. Whatever tax concessions is

Continued on Pg 41

available in the market currently do not do as well, according to this diabetologist.

Nutritionists on the other hand feel that pharma companies need to be more responsible when manufacturing medicines. Along with medicines, booklets or pamphlets should be distributed where tips can be shared like what to eat and how to feel good.

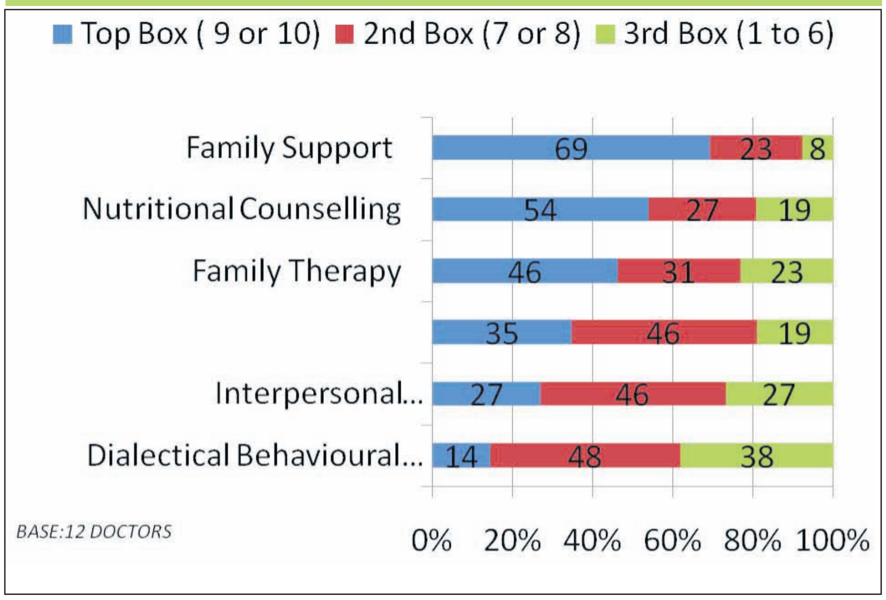
There are a number of myths on ED, which needs to be busted.

(I) EDs are not an illness and are by choice (ii) ED is a normal adolescent behaviour, (iii) Recovery from ED is rare, (iv) Only people of high socio economic status get ED, (v) Achieving a normal weight means ED is cured (vi) eating disorders are hereditary.

Doctors are of the opinion that pharma companies can play an important role in this. By setting up camps, conducting free counselling and seminars, more information on ED can be shared. Hotline numbers are popular among the specialists, where patients can be counselled while providing anonymity. 28 out of 30 doctors surveyed felt that the medications should be more effective with a reduction in side effects like feeling of sedation, tiredness etc.

The media can also play an important role in spreading awareness about ED. The medical fraternity who participated in this survey observed an increased awareness of ED among colleagues and society. This could be increased with the help of media (TV and radio being the most popular and effective modes), holding camps in college campus' which provide free counselling and checkups. Above all, it is important for families and parents to ensure that their children understand that they are beautiful as they are and do not require a 'size zero' figure to gain acceptance in society. As they say, it is always mind over body.

Important therapies



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High hopes from Union Budget...

Continued from Pg 38

available should be provided to the investing community so that they will be encouraged to do business in India. After all, the failure in this industry is about 70 per cent. Start-ups should be encouraged with low cost incubators and it should be better regulated. Tax concessions on R&D and Intellectual property (IP) should be a priority. Import of materials necessary for this industry should be facilitated. Especially for research as well more cold chains should come about. Investment on retraining manpower in government institutions to attract public private partnerships is another area of investment. Right now, these institutions are extensions of Indian bureaucracy and, hence, partnership with private institutions becomes difficult. Returning Indian talent will need funds to start new ventures for which the Government can create funds.

'We are hopeful that through this budget, the government would enable a policy environment that would encourage and support innovation'

Dr Cyrus Karkaria
President – Biotechnology
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According to various reports, the consumer spending on healthcare is set to increase to about 13 per cent of GDP by 2015. It is thus imperative that the government realises the importance of healthcare for India's growth and gives it the priority or infrastructure status. Last year, the Union Budget increased the allocation from ₹ 22,300 crore to ₹ 26,760 crore for the healthcare sector. The move was certainly a step in the right direction but not a sufficient one, in the current context. The Government should aim at increasing the public and private combined healthcare spend to seven per cent of the GDP over the next three years.

The biotechnology sector, which holds immense promise, is at present facing delays in drug development because of the present regulatory framework. We are hopeful that in this year's budget, the Government would enable a policy environment that would encourage and support innovation. In order to leverage and sustain this opportunity, the Government should focus on developing and harnessing the IP potential of the country by incentivising R&D through a weighted reduction in tax breaks to close to 300 per cent levels. A focus on breakthrough research will give the requisite fillip to R&D efforts in the country and give us an edge over other nations.

Additionally, a waiver on the Excise Duty front will help in the overall development of the healthcare industry, thus aiding in boosting exports to other markets globally. The industry could also benefit tremendously if the government can grant tax holidays, especially for R&D in pharma, and give more clarity on the direct tax code and disinvestment in SEZ's. Preferably, a status quo, with respect to subsidies, needs to be maintained in the SEZ policy to accelerate growth in the industry. Additionally, rationalisation of transfer pricing audits, customs valuation and drug pricing regulations will give a further boost to drug companies. The pharma industry is demanding R&D support from the Government, since R&D is the backbone for an industry's growth. Also, we are keeping our fingers crossed on other debated topics like whether GST will come in place, tax incentives for outsourced manufacturing activities and reduction in litigation and administrative burden among others. Will all these demands be accepted in the upcoming budget or not, can only be seen only after the Union Finance Minister, Pranab Mukherjee, tables the final budget.

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