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India boosts CRAMS sector

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In a significant move, the government of India has slashed the tax levied on pharma products manufactured in the country by 50 percent, reduced the federal value added tax by two percent and extended tax concessions to the pharma and biotech research companies which take up outsourced research works. Some of these measures are likely to spur the growth of the Contract Research and Manufacturing Services (CRAMS) sector in India.

Baddi-A Pharma Manufacturing Hot Spot in India

For most tourists driving to the Northern Indian hill station of Shimla, 350 km north of Delhi and the former summer capital of India's British rule, Baddi used to be a pit stop at the foothills of the Shivalik mountains before the arduous 40 km winding mountain roads started. A decade ago, the federal government of India gave a special status to the tiny hill state of Himachal Pradesh which allowed tax exemption to manufacturing units set up in the state. The state government quickly set up the industrial infrastructure at Baddi, on the border with the states of Haryana and Punjab and just 40 km from their joint capital city, Chandigarh.

Baddi has never looked back since then. Companies in various sectors moved in swiftly and it became a big manufacturing hub. Pharma companies too moved in a big way and there are over 500 manufacturing units of who's who of India's pharma sector.

But in one sweep, the current Finance Minister, P Chidambaram, seems to have chipped away at Baddi's advantage by halving the excise duty on pharma goods from 16 to 8 percent all over the country. Analysts feel that this move may make many pharma manufacturers relook at further expansion of production facilities in Baddi.

In the past, with profits showing the downward slope and with the steep excise duty, close to 500 drug units from Maharashtra, Gujarat and Andhra Pradesh (their traditional base) moved their production units, catering to the domestic market, to the tax-free zones in Himachal Pradesh, Uttaranchal and Jammu & Kashmir. Industry analysts estimate that 200-odd large and medium units from these states have already moved to Baddi in Himachal Pradesh since 2004. Another 300 units in Uttaranchal and Jammu & Kashmir, making these locations account for over 65 per cent the country's $11.3 billion pharma production.

The major attractions for investors included 100 percent outright excise duty exemption for a period of 10 years from the date of commencement of commercial production (the past budget stipulated it to industries starting on or before March 31, 2007), 100 percent income tax exemption for an initial period of five years and thereafter 30 percent for companies for a further period of five years, capital investment subsidy of 15 percent on plant and machinery, applicable also to existing units.

Baddi, according to an investment review by the Himachal Pradesh industry ministry, had received an investment of over $250 million in the pharma sector. Another $225 million is being invested by 20 leading Indian pharmaceutical companies.

Amendments in the value added tax (VAT) collection rules in Maharashtra has worsened the scene for the drug units based there. Mumbai-based major companies led by Wockhardt, Cipla, Lupin, Sun Pharma, Alkem, Aristo, Nicholas Piramal and a few others have already set up their plants at Baddi. In Gujarat, the scenario was even worse. Cadila Healthcare (Zydus), Torrent, Alembic, Intas and a few others are in the process of moving to the northern states. Major players from Andhra Pradesh--Dr Reddy's, Natco Pharma, Aurobindo and several others--have moved to the new location.

With the new budget measures, companies now might look out for newer avenues and this in the long run does not spell good news for Baddi.

The unveiling of the federal government's budget for the forthcoming financial year, on the last day of February has been a century-old tradition in India. For it provides the Finance Minister an opportunity to play to the galleries and favor the industries he likes and punish those whom he hates by his taxation measures. Many of the country's path- breaking changes that impact the economy have been unveiled during this exercise which is a big media spectacle too.

So the show was on air on February 29, 2008 and India's Finance Minister, P Chidambaram opened his goodies bag at 11 a.m. And one of the beneficiaries of the government's kind attention this year has been the pharma and biotechnology sectors.Especially for the industry which was crippling under the obsolete price regime, increasing competition and rising cost in raw materials. India's emerging role as being the preferred destination for drug development coupled with an increasing need to bring down drug prices have been the key factors in this year's budget sops. "The sops have come as a pleasant but welcome surprise and have more than met industry expectations," commented Dr Kiran Mazumdar-Shaw, CMD of Bangalore-based Biocon Ltd, India's No. 2 biotech company.

Most importantly industry experts, looking in hindsight predict that the budget will have a major impact on the manufacturing segment of the industry with reduction in excise duties, federal sales tax, and reduction of customs duty on life saving drugs. "This is a very unique budget that shows fiscal responsibility and gives the right impetus for manufacturing, research and development and also expands the scope of Public-Private-Partnership. I give a 10 out of 10 to this budget," opined Habil Khorakiwala, chairman, Wockhardt Pharma, Mumbai. It is a good signal that the biotechnology and pharmaceutical industry does occupy an important space in the Government's yearly budget agenda.

The booming manufacturing industry

The manufacturing sector has always had an important bearing on the overall growth of the Indian biotechnology industry. This is exactly what the Finance Minister has taken into consideration in this year's budget.

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Indian companies like Biocon, Bharat Biotech, Biological E, Serum Institute and Shantha Biotechnics have world-class facilities for biopharmaceutical manufacturing. Earlier there was some reluctance to award contracts to Asian biopharma manufacturers because of concerns of IP and regulatory compliance. But now some of the Asian countries are changing and becoming very competitive in biopharma manufacturing.

"Indian firms are expanding and scaling up manufacturing capacities to become global players and the West is increasingly becoming comfortable with the IP, quality, regulatory filings and the infrastructure here," said Gautam Das, COO, Syngene, the Bangalore-based Biocon Group's CRAMS unit . Shasun Chemicals, Suven Life Sciences, Strides Arcolabs, Jubilant Organosys, Orchid Pharmaceuticals and many other large Indian companies have started undertaking contract manufacturing of APIs as part of their additional revenue stream. Top MNCs like Pfizer, Merck, GSK, Sanofi Aventis, and Novartis are dependent on Indian companies for many of their APIs and intermediates.

Take the instance of some of the top-manufacturing units. Serum Institute of India, Pune, is widely recognized as a world-class contract manufacturer and is able to deliver a wide range of products and clinical assistance to companies on a competitive basis. In particular, Serum Institute has developed the complete process of fermentation, purification and manufacture of polysialic acid for Lipoxen PLC, a UK-based biopharmaceutical company specializing in the development of differentiated biologicals, vaccines and anti-cancer therapeutics drugs, which entered into a Development and Manufacturing Agreement (DMA) with the Serum Institute of India. Pursuant to the DMA, Serum Institute develops the technology for the manufacture of polysialic acid and its derivatives, complying with USFDA standards on a commercial scale to meet the demands of the company's collaborative partners and for pre-clinical and clinical trials purposes. Oncological products for the US and EU markets are also expected to be manufactured at the new facility.

Similarly, Wockhardt has a contract-manufacturing relationship with Amylin and many other leading pharmaceutical companies, such as Aventis and AstraZeneca. It has manufacturing plants in India and the UK, which are certified by the USFDA and the UK's MHRA.

Jubilant Organosys, the largest player in pyridines worldwide, has signed a multi-million dollar long-term agreement with Syngenta for the supply of pyridines. The new contract will begin from early 2008 and it will cover an extension period of up to five years, during which Jubilant will continue supplying the products to Syngenta. Recently Jubilant expanded its production capacity for pyridines and picolines to 42,000 TPA and this contract with Syngenta would significantly improve the use of the additional capacity.

Against this background, the measures will be a big boost for these manufacturing units growing at an astounding pace.

"All in all the pharmaceutical companies irrespective of size, scale and geography will largely benefit from these measures," said Utkarsh Palnitkar, Partner & Industry Leader, Health Sciences Practice, Ernst & Young, Hyderabad.

A report prepared by a leading investment bank mentions that the positive impact will be seen on stocks of companies like Panacea, GSK, Ranbaxy, Sun Pharma, Biocon, Cipla and Matrix. The report further states that increase in budget allocation for polio elimination program $250 million and for AIDS control program $240 million could be positive for companies like Panacea Biotec, Matrix, Ranbaxy, and Cipla.

With the excise duty on all goods produced in the pharmaceutical sector reduced from 16 percent to 8 percent, pharma manufacturing units are sure to witness a positive impact in their productivity. "Reduction of excise duty to 8 percent on all drugs and custom duty on life saving drugs to 5 percent should result in reduction of manufacturing costs and affordability of drugs. This may in turn spike the demand and may lead to higher growth for whole sector," added Hitesh Sharma, Partner, Health sciences Practice, Ernst & Young.

The announcement of allocation of funds for the polio eradication and control of HIV/AIDS is a positive sign for companies like Cipla (which has a strong presence in the manufacture of anti-AIDS drugs) and Panacea Biotec. In fact, AIDS has always been on the priority list for the governments in the past. For two consecutive years between 2003 and 2005, the government had introduced exemption of excise duties on anti-AIDS drugs along with other life saving drugs.

The Union Budget has a number of positives for the pharma biotech industry, mainly the reduction of Cenvat to 8.24 percent, the 125 percent weighted deduction to outsourced research, reduction in customs duty on raw materials for ELISA kits to 18.72 percent and select vaccines and select bio-therapeutics to 9.36 percent.

"The Life Sciences sector particularly has a lot to benefit across the spectrum. These measures will provide a great impetus to the industry. The decrease in excise duty was a long standing demand which has been met. The withdrawal of excise duty on life saving drugs and reduction of customs duty to 5 percent on these drugs was eagerly sought and this is another demand of the pharmaceutical sector that has been addressed by the Finance minister," added Ernst & Young's Palnitkar

Biotech industry association, ABLE sees many positive outcomes for the biotech industry. It stresses that the 15 percent increase in the allocation for the health sector should be a good boost for the pharmaceutical sector of the biotech industry which should result in increased usage of biotechnological products like vaccines. Several reliefs provided in the taxation proposals are also seen as generally positive. The reduction in the CENVAT rates will provide a boost to all manufacturing activities, including those in this sector. Commenting on the budget Dr KK Narayanan, President of ABLE and the Managing Director of Metahelix said, "The weighed average deduction of 150 percent on R&D that has been extended to seed production activities will provide relief to the seed companies of the bioagri sector of the industry"

Diagnostic manufacturers hit

Manufacturers in the biotech space will be hit slightly. Take the instance of Tulip Diagnostics which had recorded sales of $42 million in 2006-07. About 55-60 percent of the company's revenues come from international markets. "We have two key issues. With the dollar weakening against the rupee, we have lost about 10-12 percent in revenues in terms of the dollar value. There is nothing in the budget which looks into the fall of the dollar. China is able to do it inspite of current aggregate surplus demand and dollar surplus but India with only 1/7th of dollar surplus is still letting the rupee fall," said DG Tripathi, MD, Tulip Diagnostics.

TransAsia BioMedicals, whose sales stood at $38 million last year, was also at the losing end. "The exchange rate is very high and in the last 18 months we lost about 20 percent of the business on competitiveness. Further, the shooting salaries because of shortage of trained manpower have put us in a tight spot," said TransAsia's MD, Suresh Vazirani.

India-China: The Past and the Present

The uncompetitive nature of the Indian pricing structure had given its Chinese counterpart the upper hand. China was and still continues to be the first preference of choice for global companies. "China rules the roost and continues to be the kitchen for the US market," observed an expert. A Mckinsey Quarterly clearly mentions, that post 1980, China grew at a lightning speedy and pushed forward its GDP growth on the basis of its manufacturing industry. GDP growth had increased to 9 percent in 2003 from 8 percent in 2002. It used its domestic savings to build its infrastructure and attracted foreign investment to build factories and the expertise. Chinese biotech industry has a strong back up with companies in the US. Added to this, there are a lot of Chinese scientists settled in the US and they are taking back a lot of investments into China and further linking the Chinese low manufacturing units to high revenue markets in the US. India never enjoyed this advantage.

Hence as far as pricing issues are concerned, China always had the edge over India. Said Tripathi, "In China, all the biotech companies are given a subsidy of 25 percent. So a vendor is assured of a 25 percent subsidy. In India, there is nothing like that. We are penalized for everything. We are taxed heavily. Almost 61 percent of our revenues go into taxation."

"Until China came into the scene, we were quite competitive in the scenario. The competition was from the US and Europe. With China coming into the scene, we have become less competitive and not as strong as before," added Vazirani. The government's role has a major influence on development in both the countries. The Chinese government takes a keen role in deciding on the course that the companies should take, funds the industry, and is open to foreign investments. China has a strong manufacturing base today only because the government strongly supported it actively. In India, companies have emerged either because they were family owned or from the sheer spirits of entrepreneurship without much government support. In India, there is an urgent need for public-Private Investments (PPI). Moreover, till recently India has also been at a major disadvantage due to the appreciation of the rupee vis-vis the dollar rate which is a big blow for companies majorly into exports. This is one point again which the budget should have taken into account.

Narayanan Suresh with inputs from Shalini Gupta (New Delhi), Jahanara Parveen (Banglaore) and Nayantara Som (Mumbai)