UNION BUDGET 2012-13 TO ENCOURAGE PHARMA COMPANIES TO INVEST MORE IN R&D

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Union Budget 2012-13 to encourage pharma companies to invest more in R&D

The Finance Minister in the Union Budget 2012 has proposed to extend the tax exemption for in-house R&D by another 5 years to 2017 to encourage pharmaceutical companies to invest more in R&D. At present, companies engaged in certain businesses are eligible for a tax deduction of 200 percent on certain expenditure incurred by them on in-house R&D facility. This deduction was to expire on March 31, 2012. The pharma industry had demanded extension not only due to the importance of innovation but also because the implementation of the Direct Tax Code, the new proposed legislation that will replace the existing Income Tax Act & Rules, has now been delayed.

PSA view – The 5 year extension will surely benefit and encourage further R&D efforts. India is already a global R&D hub and this move shall surely increase the global investment in the Indian pharma sector. However, increase in service tax from 10 to 12% will directly have impact on all industries, particularly the pharma sector. There is no special incentives to increase productivity. The increase in excise duty will result in hike in prices of medicines as the manufacturers will pass on the excise burden to the consumers. The reduction of customs duty from 5% to 2.5% on medical devices and CVDs such as stents and valves as well as customs duty reduction on vaccines, lifesaving and anti-cancer drugs is also a welcome measure.

New look at the Jan Aushadhi Scheme

The Department of Pharmaceuticals ("**DoP**") had announced a campaign for making available cheap generic drugs through establishing a network of Jan Aushadhi stores far back in 2008. Now 4 years later, the growth of the campaign has been slow and only 112 such stores have been opened in the 11 States of India, as opposed to the target of accomplishing establishment of 612 stores within a period of two years all over India. Owing to this, the DoP had submitted a revised business plan to the Planning Commission. A Steering Committee of the Planning Commission which reviewed the business plan has recommended allocation of 200 crores to salvage the initiative.

PSA view – The initiative of the DoP is aimed at procuring unbranded generic drugs at a lower cost than branded drugs to ensure availability and accessibility to the common man. While the implementation of this plan has failed drastically, there need to be positive steps taken by the government and the drug authorities to put the plan back on track. The infusion of funds into the project by the Planning Commission is a first step

towards achieving the objective. The DoP should also look at using this opportunity to promote the growth and development of the Small and Medium scale manufacturers by sourcing the drugs from those who are Schedule M compliant, and not limit the scope of procurement to generic drugs but also include certain life saving drugs under the Jan Aushadhi Scheme.

Compulsory license: foreign companies worry or the balancing act?

India's first compulsory drug license was granted on March 12, 2012 to Natco Pharma to manufacture and sell its low-cost version of a cancer drug at a fraction of the price charged by patent holder Germany's Bayer AG. The CL was granted in response to an application filed by generic manufacturer Natco Pharma nine months ago requesting authorization to manufacture and market generic versions of the kidney and liver cancer medicine, sorefanib tosylate. With this the fear that the Indian patent law does not protect the intellectual property of foreign investors has increased and also that the local laws does not encourage foreign investors. Last year, there was a move to restrict FDI through M&A and it was finally decided that all M&As undertaken by foreign drug firms must be cleared by the Competition Commission of India. The DoP is currently finalizing a new drug pricing policy for India. The basic aim of this policy is also to do away with the dual pricing policy norms for local and imported brands – a move that can further bring the foreign pharma companies to tenterhooks.

PSA view – The Indian Pharmaceutical Alliance, the body that represents Indian drug makers has welcomed the compulsory license step as a balancing act. In effect, if we analyze the situation, Natco's drug costs only 3% of the Nexavar's price. MNCs are generating enough profits and cannot afford to stay away from Indian market. So, steps like a couple of compulsory licenses will not deter them to further invest in India. Novartis has been fighting a legal battle to challenge the rejection of its patent application for its cancer drug Glivec. This case is due for hearing on March 28, 2012 before the Supreme Court of India. In this controversial case, the Swiss pharma major is challenging Section 3(d) of Indian Patents Act which prohibits "evergreening" – the practice of multinational pharmaceutical companies to extend their patent terms by making small and trivial changes to existing molecules and thereby preventing manufacture of generic drugs.

Some crucial developments last month

- To further promote the rational use of drugs particularly in key therapeutic areas, the Health Ministry is mulling the idea of framing treatment guidelines for diseases like HIV, TB and Malaria programs which will be made applicable not only in the government centers that are extending treatment for HIV and TB, but also for the private health facilities and providers.
- As part of strengthening the infrastructure to fight the menace of spurious and substandard drugs, the authorities are planning to launch mobile drug testing labs in the country soon. The Central Drugs and Standard Control Organization has already submitted a detailed proposal for introducing 20 mobile laboratories that would move around the places to help the drug inspectors collect the samples and carry out tests instantly.
- Karnataka government may soon come out with a set of dedicated State Drugs and Cosmetic Rules under the Drugs & Cosmetics Act 1940. An expert committee for this purpose has been formed with the mandate to finalize these draft Rules shortly. The key purpose of this Rules would be to bring in a strict and rigorous system of audit, inspection and booking violators of the law. The new rules are

extremely urgent going by the changes taking place in the pharma and biotech industry. The State Drugs & Cosmetics Rules could also be relevant for the country as it is also looking to define specific area for pharmacy outlets.

- The proposal to cap the prices of essential drugs as per the government procurement rates, instead of the market based pricing as proposed in the draft pharmaceutical pricing policy, is unlikely to get the nod of the Group of Ministers because of the huge difference between the market prices and procurement rates.
- The Indian Council of Medical Research ("**ICMR**") will soon come out with the new revised and final **Guidelines for Stem Cell Research and Therapy** providing ethical and scientific directions to scientists and clinicians working in the field of stem cell research in the country. Earlier in June last year, the National Apex Committee for Stem Cell Research and Therapy, constituted by the Union Health Ministry early last year for effectively reviewing and monitoring the stem cell research in the country, had decided to revise the Guidelines for stem cell research regulation in the country. The ICMR and the Department of Biotechnology jointly had formulated Guidelines for Stem Cell Research and Therapy in the year 2007 providing ethical and scientific directions to scientists and clinicians working in the field.

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