GOVERNMENT PLANS NEW LEGISLATION TO TAKE DPCO OUT OF ECA AMBIT

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The government plans to bring a new legislation for price control and monitoring of drugs. The Drugs Price Control Order ("DPCO") which is presently mandated under the ECA would be swapped by specific legislation covering the issue of price control and monitoring of drugs. The new policy, aims to bring 348 essential drugs under price control. The National Pharmaceuticals Pricing Authority will be the implementation authority for the new policy and the new DPCO. According to the existing DPCO, the pricing regulator fixes prices of 74 bulk drugs, and all medicines containing one or more of these bulk drugs. However, the existing drug pricing policy will only be replaced over a period of time.

PSA view – Finally it seems that the government is taking necessary measures to have a pragmatic policy of fixing prices of drugs which is considered essential through the proposed legislation. The proposed method will take into account market-based data while fixing the Ceiling Prices ("CP") of the drugs. However, if the ambit is increased to 348 essential drugs the same may prompt pharmaceutical companies to cut down spending on research.

DGCI takes tough stand on FDC's

The DGCI has taken a tough stand on FDC manufacturers and have asked manufacturers to prove the efficacy and safety of the drugs being manufactured by them. In late 2012, the DGCI had asked the state drug controllers to seek the safety and efficacy reports from drug manufacturers. This action has come in play because of the report of the Parliamentary Standing Committee on the functioning of the CDSCO which noted that several state drug controllers have provided licenses for manufacture of a large number of FDCs without any testing for safety and efficacy, putting patients health at risk.

PSA view – The action by the DGCI is in the interest of the patients and will improve the quality of the general health care in India. However, such an action is more so in the nature of damage control than avoiding such dangers at all. There are already FDCs available in the market and have been purchased and consumed by the public at large. Wider publicity needs to be carried out by state drug controllers relating to the FDCs whose efficacy has not been tested and in order to avoid such a situation in the future, the state drug controllers, in whose jurisdiction any FDC has been found to be unsafe or ineffective, should be penalized.

License to operate from FSSAI made mandatory for restaurants, eateries and canteens

It has been mandatory for all eateries in the country to obtain a Food Business Operator license from the central food authority, FSSAI by February 4, 2013, post which the FSSAI shall conduct random checks across the country to ensure compliance with this requirement. If a restaurant is found without licence, the authority can penalise it and even have it shut down. This move is surely to effect many eateries who are complaining that compliance in such short period would not be possible and the procedure to obtain the license needs to be more user-friendly. On the contrary the FSSAI officials are adamant that the deadline date will not be moved further as the procedure had commenced in August 2011 thus giving the eateries ample time to comply with the requirement. The licence will require all eateries to fulfil certain compliance measures which include requirement to install chimney to ensure no smoke in food areas, follow systematic cleaning schedules, follow procedures in sourcing raw material from dealers, install specific temperature control storage facility for frozen and cooked foods, to name a few.

PSA view – Food safety has been a perennial challenge in India with frequent cases of food adulteration and food poisoning. Indeed the short time span will lead to eateries queuing up to obtain the license, which could lead to FSSAI being over-burdened with the applications and thus leading to delay in issuing the same. However, this surely is a move in the positive direction as the license will require compliance with series of stringent guidelines including specific hygiene practices.

CDSCO to cancel license of drug manufacturer if they fail to launch their product within 6 months

TheDCGI has sent notices to all state licensing authorities to implement an order that the CDSCO will cancel the permissions and licenses given to the drug manufacturers who fail to launch the particular product for marketing in the country within a period of six months after obtaining the permission from the CDSCO. Under the Drugs and Cosmetics Rules, 1945, permission to manufacture a new drug is granted by CDSCO and based on this permission manufacturer obtains manufacturing license from the concerned State Licensing Authorities. As per Schedule Y, periodic safety update reports (“PSURs”) of new drugs are required to be submitted every six months for the first two years after approval of the drug is granted.

PSA view – This decision seems logical as if the manufacturer fails to launch its product within six months, it will not be able to submit the first PSUR on time. PSURs are important for assessing the safety and efficacy in post marketing scenario and delaying the launch does not allow the assessment to be done.

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