PLANNING COMMISSION RECOMMENDS CENTRAL DRUG AUTHORITY FOR STRENGTHENING DRUG REGULATION

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Planning Commission recommends Central Drug Authority for strengthening drug regulation

The SC of the Planning Commission established to finalize the 12th Health Plan for the Ministry of Health and Family Welfare has recommended the constitution of a CDA to weed out irrational fixed dose combinations and for implementing an effective e-governance system. The recommendation follows the Mashelkar Committees report for establishment of a CDA to be the central agency for issuing licenses to manufacturers and sale of drugs. The SC has also recommended that the drug regulator needs to accord priority to pharmacovigilance, adverse drug response monitoring, quality control, testing, revaluation of registered products and post marketing surveillance. The SC has further recommended that medical devices be included under the Drugs and Cosmetics Act for according risk based classification and regulation of clinical trials, conformity assessments and penalties specifically for medical devices.

PSA view – The recommendations of the SC, while are aimed at providing at simplifying drug administration in India, may complicate matters further. There are multiple departments and organizations with prescribed mandates regulating aspects of drug administration, manufacture and sale in India, and creation of a new body centralizing all these functions, while appears to be simple and efficient, is likely to cause overlap and confusion. Instead of formation of another body centralizing the functions already being carried out by different agencies, there needs to be better co-ordination between different wings of the departments and focus on priorities. Now that the SC has provided its recommendation, only time will tell whether another cog is added to the drug administration machinery or whether appropriate priority is accorded to pharmacovigilance, adverse drug response monitoring, quality control, testing, revaluation of registered products and post marketing surveillance of drugs and medical devises.

The FIPB still the authority to regulate FDI in brownfield investment in pharma sector

In October 2011, it was reported that at a high level meeting convened by the Prime Minister (“PM”) it was decided that brownfield investments in the pharma sector would be allowed through the FIPB for six months following which acquisitions would be routed through the CCI. However, further to a meeting convened by the Commerce and Industry Minister on April 12, 2012 it seems that CCI is still not in a position to regulate FDI as even after six months of the announcement by the PM it doesn’t have the necessary legal mandate

and thus carries the risk of running into litigation if it controls FDI. Therefore in light of the above, the FIPB is still the responsible authority to regulate brownfield investment in India.

PSA view – The move to allow CCI to handle brownfield foreign investment has been heavily criticized by not only the industry, but also by the ministry of finance, pharmaceutical and even the planning commission. The argument against permitting CCI to regulate FDI is that by doing so CCI will not be able to concentrate on its primary function, i.e. that of enforcing fair trade. In our view, this should not be the only reason for opposing CCI from regulating FDI in brownfield investments. It is to be noted that there already is an authority which has been specifically created for promoting and regulating foreign investment in India, namely the FIPB, and there is no requirement to assign the task to a different body. Further, by allowing the CCI to regulate FDI in brownfield and FIPB to regulate FDI in greenfield investment, unnecessary confusion will be created. It is best advised to let the FIPB handle the entire FDI regulation and let CCI concentrate on enforcement of fair trade.

Some crucial developments last month

i. The Indian Council of Medical Research ("ICMR") has issued guidance on the submission of papers and documents for the purpose of transfer of human biological material for commercial purposes and/or research for development of commercial products. The evaluation of cases will be a continuous process and the ICMR will process the applications four times in a year. A committee has been constituted to consider the cases related to transfer of human biological material for commercial purposes which shall consider the cases where infectious biological material/samples are proposed to be transferred from foreign research centers to Indian diagnostic laboratories/research centers or vice versa for analysis; transfer of human biological waste material or any other cases for commercial purposes.

PSA view – Irrespective of the guidance document of ICMR, for transfer of samples, the Indian applicants will have to follow the "Guidance on regulations for the transport of Infectious substances (2009-2010)" as published by WHO. Specific packing instructions/specifications are to be followed during transport of infectious substances and unless declared the biological materials such as blood and/or blood components; dried blood spots and faecal occult blood; medical or clinical wastes shall be considered under the "infectious substance category."

ii. The Clinical Establishments (Registration and Regulation) Act has officially been made into effect in Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union Territories with effect from March 1, 2012, enabling them to take necessary steps for the implementation. The Centre has requested other States to adopt this law. The registration of clinical establishments would help the government to build a database for hospitals, which in turn would assist in formulating the national policies on health. The hospitals and clinics would be categorized according to the facilities available with them and their database along with costs would be put on the websites.

PSA view – As health is a state subject, states have the primary responsibility to regulate and monitor the functioning of clinical establishments in their respective states. As these four states had authorized the Centre to legislate the rule in this regard, they brought this legislation into effect, while it is facing stiff opposition from all other states.

iii. The government has set up a central procurement agency as a society, in the name of Central Medical Services Society ("CMSS") which is expected to start functioning in the financial year 2012-13. CMSS shall function as an independent, professional and autonomous agency for procurement of quality health sector goods and services required by the Department of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India in a transparent and fair manner and make goods available at convenient locations for the benefit of users by addressing efficiently the supply chain issues.

PSA view – CMSS is likely to eliminate the existing deficiencies and streamline the drug procurement and distribution system in India. Presently, the health ministry procures drugs and vaccines; however, inadequate professional procurement expertise, absence of supply chain management system, manual collection of data and absence of any credible management information system have been adversely affecting the procurement system. This is expected to change with CMSS.

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