SEPARATE DRUG CONTROLLER UNDER AYUSH MINISTRY ON THE CARDS

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Department of Indian Systems of Medicine and Homoeopathy (ISM&H) which was created in March, 1995 and re-named as Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy ("AYUSH") in November, 2003 was constituted with a view to providing focused attention to development of Education & Research in Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy systems. The Department will soon witness upgradation on the regulatory front. We already know that the new government had done a laudable job with the creation of a separate portfolio for AYUSH. Now, the Union Ministry is proposing to have a drug controller at the Centre for AYUSH. This will put in place a separate regulatory regime for Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy which were till now governed by the drug controller of modern medicine. It has been reported that the budgetry allocations for Ayush which were until now very meagre at about Rs. 400 crore for fiscal 2014-15 will soon be elevated to Rs. 2,700 crore for the next fiscal, beginning April 2015.

Union minister for Ayush, Shirpad Yesso Naik stated in a recent public event, "The drug controller for AYUSH would be provided with sufficient teeth to regulate the AYUSH as per new policy prescription, who would also be provided with a mandate to issue the Certificate of Pharmaceutical Products (CoPP) for export of AYUSH products…Recruitment rules are being finalized for the new drug controller and cabinet note being finalized for new regulations of AYUSH products under the new AYUSH health policy which would be unveiled very shortly",

PSA view – Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy have been India's forte and it's high time we take this stream of medicine seriously. It is indeed great to see the government doing something beyond just propagating this field in various conferences and seminars. It will be interesting to see the new set of rules and regulations for sale, manufacture, labeling, distribution, testing and quality control of AYUSH drugs. We won't be wrong in stating that the sector is still untapped and going forward, if we take a well blended commercial-cum-welfare centric approach, the Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy segment of drugs will be highly beneficial for our pharma sector.

AIMED Recommends re-Drafting of Drugs and Cosmetics (Amendment) Bill, 2015

The Union Ministry of Health and Family Welfare (the "Ministry") had released the draft Drugs and Cosmetics (Amendment) Bill, 2015 (the "Bill") to amend the Drugs & Cosmetics Act, 1940. Early, this month, the Ministry had invited suggestions on the Bill from all the stakeholders of the pharma industry. In this context, the Association of Indian Medical Device Industry (AIMED) has raised certain concerns regarding the scope and

effectiveness of the Bill for improving medical device industry and urges the Ministry to re-draft the Bill according to their recommendations.

The recommendations put forth by AIMED includes: (i) the bill may be re-named as Medical Devices & Patient Safety Bill, 2015; (ii) the regulatory body may be called Indian Healthcare Products Regulatory Authority with separate divisions for Drugs, Cosmetics, Medical Devices & Diagnostics; (iii) revise the definition of manufacturer which includes “manufacture through another Person on his behalf” as it aides the foreign players to claim their dominance in the Indian market and thus, contradicts the goal of “Make in India”; (iv) include a representative of the Medical Device Industry and National Accreditation Board of Confirmatory Assessment Bodies in the Drugs, Cosmetics & Medical Devices Consultative Committee; (v) must provide for a transition period for the implementation and compliance of the new regulatory provisions by the manufacturers; (vi) power to impose commercial punishments on registered and licensed manufacturers by regulatory authority, and; (vii) clarity on procedure to regulate notified category of medical devices under the Bill.

PSA view – The Bill aims to regulate the import, manufacture, distribution and sale of drugs, cosmetics, medical devices and conduct of clinical trials and for matters. However, in reference to the AIMED’s recommendation, necessary steps must be taken by the Ministry to re-define the definition of manufacturers, lay down effective procedure to regulate notified category of medical devices and adopt manufacturing compliances favorable for domestic manufacturers to ensure not only patient safety but also promote competitiveness in the sector.

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