NEUTRACEUTICALS GUIDELINES IN THE PIPELINE

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These days, the demand for special food items like neutratceuticals and dietary supplements has increasingly been growing by leaps and bounds. The FSSAI had recently constituted Task Force to device a regulatory framework for regulating supply of these products in the market. Task Force's recommendations primarily comprise guidelines for the approval of dietary supplements and neutraceuticals that are manufactured and marketed across the country. Once the recommendations get a nod from the FSSAI, all the manufacturers across the country will have to seek NOC from the Centre prior to manufacturing neutraceuticals.

PSA view – As of date, there are no laws to regulate this segment of the market. A lot of incidents have been reported regarding the adverse effects that the "so-called" ayurvedic and Unani products have on people. We are hoping that the new regulations have enough teeth to check the capability of neutraceuticals' manufacturers who claim to churn health related products. Since these products aren't usually recommended by doctors and are purchased over the counter, the constituency and effects/side-effects must be clearly written on the packaging, as in case of allopathic drugs. As of now, let us wait and watch!

Vigilance mechanism programme for medical device industry to be introduced soon

The Union Health Ministry ("Ministry") as a step to regularize the medical device industry has proposed to introduce the Materio-Vigilance Programme of India ("MvPI") in 3 months to create a mechanism ensuring safety of medical devices among the public. MvPI programme will be specific to the medical device industry and is intended to function in tune with the existing PvPI programme and haemovigilance programme.

The Ministry wishes to kick-start the programme by setting up MvPI cells in 10 medical colleges. The proposed programme primarily focuses on creating a system for reporting medical device associated adverse events, create awareness among the health care professionals on reporting requirements, formulate system for data collection and storage and provide a platform to stakeholders to access to its recommendations.

PSA view – The Ministry's decision to formulate a vigilance mechanism specific to medical device industry is a step in the right direction. Lately, the Ministry has introduced several amendments in the pharma related legislations to promote and protect the medical device industry and hence, this step to create strict reporting and vigilance mechanism will assist in effective implementation of these legislation. Hence, the MvPI programme is a welcome move.

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