THE HEALTH MINISTRY MAY NOT ISSUE DIRECTIVE U/S 33P TO SLAS ON SPURIOUS DRUGS ACT GUIDELINES

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In September 2010, the Union health minister announced that the Union Health Ministry (**"Ministry"**) would implement the Spurious Drugs Act by issuing a directive to the state drug authorities under section 33P of the Drugs and Cosmetics Act, 1940 (**"Act"**) under which it would be mandatory for the state drug authorities to follow the guidelines before executing the various provisions of the Spurious Drugs Act. Now, the Ministry is reconsidering this decision. It is planning to issue a general directive to the state drug authorities stressing the need to consult the guidelines attached to the Spurious Drugs Act before initiating any prosecution against the manufacturers for manufacturing and marketing spurious drugs.

PSA view – The industry wants these guidelines to be made mandatory as it would ensure that the genuine manufacturers are not harassed. The Ministry feels that the concerns of the industry can be addressed by issuing a general direction to the state drug controllers. The government must stick to its earlier decision of issuing directive under section 33P of the Act and notify the guidelines.

*** FSSAI taking proactive measures**

FSSAI's released **(i)** an approach paper regarding the drawing up or revision of food standards in India; **(ii)** an advisory on standards for honey and prohibition of antibiotics; and **(iii)** instructions regarding the application of the Prevention of Food Adulteration Act, 1954 and other Acts for the clearance of consignments of food articles. The Customs shall, in addition to testing of samples, check for all perishable items – **(i)** the condition of the products when transported for the requirements of storage as per the nature of the product, **(ii)** contamination of the products, and **(iii)** the labeling requirements under the Prevention of Food Adulteration Rules and the Packaged Commodities Rules. Pending receipt of test report, such consignments may be allowed to be stored in warehouses under section 49 of the Customs Act, 1962.

PSA view – These documents shows the way FSSAI has become active in organizing the food sector in India. They are keeping a strict vigil on every aspect of the food industry and issuing necessary guidelines to bring a uniformity and compliance in the practices followed. Importantly, the move on the perishable food items was crucial as perishable food items like fruits, vegetables, meat, fish, cheese, etc. have quick turn over and which, once opened, can lead to quick spoilage, if not kept in refrigerated conditions.

*** Pharmaceutical Technology Upgradation Assistance Scheme by early 2011**

The DOP is in the process of launching the highly anticipated Pharmaceutical Technology Upgradation Assistance Scheme (**"PTUAS"**) by early half of 2011. The PTUAS is likely to assist over 200 medium scale

pharmaceutical manufacturers in becoming compliant with the WHO-GMP and other international norms. The DOP has outlined an initial assistance requirement of INR 100 crore (*USD 21.5 million approximately*) for upgrading the medium scale pharmaceutical units. At present, the DOP proposes to make the PTUAS operational only for a period of one year from the date it is announced, however it may be extended, keeping in mind approximately 1,200 medium scale pharmaceutical manufacturing units in India. The scheme essentially facilitates financial assistance to pharmaceutical manufacturers that have applied for loans for technological up-gradation to above WHO-GMP and other international norms. The scheme will offer a reimbursement of five percent of interest points on the loans taken from banks and financial institutions.

PSA view – The PTUAS is a novel measure by the DOP for facilitating and promoting upgradation of the medium scale pharmaceutical manufacturers, which accounts for a majority of the pharmaceutical exports. By inducing the pharmaceutical units to upgrade to standards higher than the WHO-GMP, the DOP has attempted to make Indian manufactured pharmaceutical products more viable for domestic consumption and for international sale. This in turn will benefit the pharmaceutical units as well as balance out foreign trade in India's favor. However, with a proposed cap of INR 100 crores (*USD 21.5 million*), the number of units that will be able to take effective advantage of the scheme remains to be seen. The DOP may have to revise and increase the figure of INR 100 crores or accordingly adjust the 5% points subsidy.

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