EXPECT AMENDMENT IN THE DRUGS AND COSMETICS ACT TO CURB PHARMA COMPANIES FROM GIVING FREEBIES

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Under the regulations (as recently notified by the Medical Council of India (**"MCI"**)), only doctors accepting gifts from pharmaceutical companies are liable to be penalized. The pharma companies who give such gifts are beyond the scope of law. The MCI is now keen to check this practice (*mal*). MCI's proposal to the Union Health Ministry to amend the Drugs and Cosmetics Act to bring the pharmaceutical companies under the purview of law, by making them punishable for rolling out freebies to doctors for promoting their medicines, will soon be a deterrent for pharma companies. Indulging in such unethical trade practices may lead to cancellation of licenses of the pharma companies.

PSA view –

MCI had recently introduced the regulation for curbing doctors from accepting gifts from pharma companies and had prescribed penalty in terms of cancellation of their registration to practice. The new initiative to bring pharma companies under the ambit of law in which they will be punished if found guilty of giving any kind of gift to the doctors as part of their promotional activity is certainly a welcome move. The pharma companies very often extend several kinds of gifts to the doctors including holiday packages to promote their products, which actually amounts to unethical trade practice. Hopefully, the amendment will take place soon and check such malpractices.

Schedule M causing small manufactures to shut shop

According to the Ministry of Micro, Small and Medium Enterprises (**"MSME"**), the amendments in Schedule M of the Drugs and Cosmetics Rules has put severe financial strain on the domestic pharma industry. The MSME is concerned that though the compliance of the guidelines under Schedule M have been met with, it has caused many manufacturers to shut shops. The goal of the survey is to collect information on- (i) the total number of pharma units including state-wise break-up, (ii) total number of Schedule M compliant units, (iii) names of units which have been closed since July 1, 2005 due to non-compliance of Schedule M norms, (iv) cases in which licenses have been surrendered by the manufacturers, and (v) cases in which licenses have been suspended or cancelled by the authorities due to the non-compliance of revised norm. The findings of the survey will be forwarded for incorporation in the "action taken" report by a parliamentary panel.

PSA view

– Schedule M prescribes the good manufacturing practices and requirements of premises, plant, and equipment for pharmaceutical products, wherein changes were introduced in 2005 to harmonize the

production of drugs and pharmaceuticals and to meet the requirements of international guidelines as recommended by the World Health Organization ("WHO"). However, due to strenuous and ever increasing compliance requirements, many small-scale manufacturers have had to shut their manufacturing operations which in turn have benefited only the large manufacturers. Small-scale manufacturers form an important part of the pharma industry in India as it brings health care and medicines within reach of rural and lower-income groups. Once the survey is completed and the report is submitted to the Ministry, it will take appropriate actions to revive the small scale manufacturers, by either providing incentives to continue manufacture or by providing assistance to make compliance less burdensome while at the same time preserving quality of the drugs.

Working Procedures of issues to Scientific Panels and Committee ("SPC") released

SPC have been constituted by the Authority to advice on a range of scientific issues with particular reference to determination of safety standards. SPC are responsible for providing scientific opinions to the Authority based on risk assessment. The scientific opinion shall be developed in a consistent manner according to harmonized working procedures. The Authority has released a document describing the working procedure of SPC to recommend how opinions should be set out, in accordance with the principles of the Food Safety and Standards Act. Generally, the core principles in the provision of scientific advice that FAO and WHO have adopted are soundness for scientific excellence; responsibility to safeguard the integrity of the process and to consider scientists answerable for their views; objectivity – neutrality and independent opinion based on scientific knowledge; fairness of the assessment process; transparency in the design and implementation of the mechanisms of generating scientific advice and inclusiveness of minority scientific opinion and the balance of skills and expertise necessary for the assessment.

PSA view –

The general purpose of seeking scientific advice is to help risk managers, policy makers, and others in decision making process to analyze the risk involved and accordingly initiate an effective dialogue between risk assessors and risk managers for optimal advice. There should be effective dialogue between Authority and the SPC to ensure that questions posed to them are clearly understood and will finally help the Authority in the development of its policies and regulations.

Authority issued licenses to cover certification of processed foods

The various food safety and assurances schemes for food processing industries – (i) Fruit Products Order, 1955, (ii) Meat Food Products Order, 1973, (iii) Milk and Milk Products Order, 1992, (iv) Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967, (v) Vegetable Oil Products (Regulation Order, 1998, (vi) Edible Oils packaging (regulation) Order, 1998, etc that regulates the various commodities of food and the (vii) Prevention of Food Adulteration Act, 1954 ("PFA") has been brought under the Authority. Also, the mechanism of certification of the processed food, issue of licenses and registration of manufactured units will be undertaken by the Authority. The applicants will have to seek registration/license under the specific order which also has the provision that empowers the authorized/technical officers to inspect the manufacturing units periodically to ensure that the minimum hygiene conditions are maintained.

PSA view – The Authority was created to bring diverse laws related to food and safety under one all-encompassing regulation and authority. The Orders have not lost their sanctity like the PFA and the Orders

are to be complied by the processed food units. Also, the samples from various units can be drawn for testing in the food laboratories to ascertain their conformity. Such measures help in maintaining and improving the overall quality and minimum standards of facilities and services in food sector. Given that the food sector has remained largely unregulated and uncontrolled in India, the law, if implemented effectively, will attempt to regulate the food sector ensuring safety and standards.

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