MAKE NO ERROR! – MANDATORY REGISTRATION OF CLINICAL TRIALS IN INDIA

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It is mandatory for all pharmaceutical companies planning to undertake clinical trials in India to register with the Indian Council of Medical Research Clinical Trial Registry. The hitherto optional registration has been made compulsory by the Directorate General of Health Services with effect from June 15, 2009.

PSA view – In light of the increasing number of adverse events, malpractices, trials by small unknown companies/hospitals, mandatory registration will ensure transparency, accountability and accessibility of clinical trials and their results to public and will also, to an extent, streamline the entire process from start to finish.

Opportunity calling in the Pharma sector

The Department of Pharmaceuticals (**"DoP"**), Ministry of Chemicals and Fertilizers, is contemplating major projects including establishment of two pharma clusters, a pharma city, a vaccine development centre and four R&D hubs to enhance the manufacturing and R&D capacity of the Indian pharmaceutical sector. The proposed actions include establishing (i) a pharma city in the state of Andhra Pradesh; (ii) R&D hubs (with incubation centre, wet labs, common facilities in line with international facilities and standards and DoP support for land allotment and for overall project) in places including Mumbai, Pune, Kolkata, and Chennai; (iii) a high end medical device cluster (including facilities like sterilization and testing systems) in the state of Gujarat, to provide technical support to the growing medical devices industry in the country. The project is expected to take off in mid-September 2009.

PSA view – Needless to say, the Government of India is keen to boost the pharmaceutical sector in terms of providing top-class facilities and infrastructure for manufacturing and R&D companies. It is an excellent opportunity for pharma companies to establish base in these contemplated clusters and gain a foothold in the industry in India.

Food companies to introduce nutritional labeling

India plans to introduce a uniform and integrated food law to address the lacunae under the existing food laws regime. As a measure to protect the general public and to supplement informed choice, the integrated food law will, inter alia, feature a requirement of nutritional labeling of food items. The Ministry of Food Processing Industry will prescribe the nutritional standards and the labeling requirements. Meanwhile, companies in the Indian food sector especially subsidiaries of foreign food giants such as Unilever, Kellogg,

and ConAgra are planning to adopt common nutritional labeling standards ahead of the implementation of the integrated food law to address growing health awareness and concerns about obesity.

PSA view – The applicable legislation, the Food Safety and Standards Act, 2006 (**"FSSA"**) has not been brought into force in totality, but once enforced, it will serve as the basis for implementation of nutritional labeling of processed food products. It is prudent for food processing companies to prepare for the change in food law regime which is expected to change soon with the complete enforcement of FSSA and coming up of the corresponding rules.

Centralized issuance of WHO-GMP certificate by the Drugs Controller General of India ("DCGI")

The DCGI has centralized the issue of Certificate of Pharmaceutical Products (**"CoPP"**) or Good Manufacturing Practice (**"GMP"**) certificate to manufacturers, which will ensure uniformity and compliance with WHO guidelines. Until now, the manufacturers had the freedom to go from one state drug authority to another for obtaining licenses in case of refusal by one. Moreover, the certificates issued by different states were many times at variance with the WHO certification scheme, or non-compliant with WHO quality standards and also created confusion in the minds of regulatory authorities of the importing countries.

PSA view – The move will certainly bring strict monitoring over the manufacturers, and their ability to produce quality products. However, it remains to be seen if the DCGI has the necessary infrastructure to dispose off applications expeditiously without hampering flow of exports. Moreover, the duration of license is for two (2) years, which means the exporters will be required to renew their license every two years, which is cumbersome. It is hoped that the regulatory authority will have an efficient system in place to issue licenses expeditiously to the large number of drug exporters and further be prompt while dealing with license renewals.

On the flip side, many small drug manufacturers may not welcome this shift as they will find it difficult to obtain license for their products since they will no longer have the flexibility to approach another state authority in the event of refusal to grant license by one state authority. On the whole, however, it is a good move for the importers, their regulatory authorities, and the quality of Indian pharma produce.

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