LEXCOUNSEL
LAW OFFICES

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LexCounsel, Law Offices

C-10, Gulmohar Park
New Delhi 110 049, INDIA.

Tel.:+91.11.4166.2861
Fax:+91.11.4166.2862

Reported here are the recent developments in the regulatory landscape of India, that are relevant for the medical professionals as well as the pharmaceutical and allied healthcare industry ("**Industry**").

Tax on Freebies to the Doctors

The Central Board of Direct Taxes, Ministry of Finance, India ("CBDT") has on August 1, 2012 directed, in effect, that the Industry as well as medical practitioners would be liable to income tax on the value of any freebies given by the Industry to the medical practitioners.

The (Indian) Income Tax Act ("IT Act") permits deduction of revenue expenditures from the business income, and thus from the resultant income tax, if the expenses are incurred exclusively for the purpose of business or profession and such expenses are not prohibited by the law.

The Medical Council of India, a regulatory body constituted under the Medical Council Act, 1956 has, by an amendment on December 10, 2009 to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 ("IMC Regulations"), imposed a prohibition on the medical practitioners from receiving any gifts, travel facilities, hospitality, cash or monetary grant from the Industry. Our analysis of the 2009 amendment is available here.

Resultantly, in CBDT's view, such freebies amount to expenses prohibited by the law, and are, therefore, inadmissible as an expense under the IT Act, attracting income tax. The CBDT has further prescribed that the value of the freebies enjoyed by the medical practitioners is also taxable as 'business income' or 'income from other sources', as the case may be, for such medical practitioners.

Government Issues Draft Regulations for Clinical Trials

Often criticized for lack of stringent regulations on clinical trials, the Ministry of Health and Family Welfare ("MoH&FW") has taken not one but three quick steps in that direction. The departments of the MoH&FW have come up with two notifications and one set of guidelines, as discussed below, inviting suggestions and objections from the public for consideration by the MoH&FW before coming up with the final set of regulations.

The notifications, viz. the 3rd and the 4th amendments to the Drugs and Cosmetics Rules ("Rules"), dated July 17, 2012, supplement the requirements for prior permission to conduct any clinical trial in India and registration of the ethics committees with the licensing authority under MoH&FW ("Licensing Authority"), respectively.

As per the 3rd amendment, the prior permission for clinical trials would be granted once the Licensing Authority is satisfied that the data submitted with the application in support of the proposed clinical trial is adequate. It also specifies that the permission to conduct clinical trial should be subject to specific conditions as may be prescribed on a case to case basis, in addition to the following general conditions:

- Compliance with the approved protocol, Good Clinical Practice Guidelines for Clinical Trials in India ("GCP Guidelines") and other applicable regulations including the relevant schedule of the Rules;
- Compliance with the "Ethical Guidelines for Biomedical Research on Human Participants" published by the Indian Council of Medical Research, New Delhi;
- Registration of the clinical trial at The Clinical Trials Registry – India before enrolling any patient in the study;
- Submission of annual status report of each clinical trial, along with detailed reasons for termination of any trial;
- Reporting of SUSARs (Suspected Unexpected Serious Adverse Reactions) to the Licensing Authority and other investigators within 14 days of their occurrence;
- Provision of complete medical care as well as compensation for any study related injury or death, with adequate mentioning in the informed consent document; and
- Details of compensation to be informed to the Licensing Authority.

The 3rd amendment widely empowers the Central Drugs Standard Control Organization ("CDSCO") to carry out regulatory compliance checks at the premises of the sponsors, clinical research organizations and clinical trials sites and to search and seize records, data as well as investigational drugs. The Licensing Authority has been empowered to issue show cause notices, warnings, directions for suspension/cancellation of the clinical trials and impose restrictions on investors/sponsors/CROs from conducting trials in the future. An appeal against any such directions may be preferred before the Central Government within a period of 90 days.

The 4th amendment seeks to prescribe for once in 5 year registration of the ethics committees with the Licensing Authority and prohibits them from reviewing or approving any clinical trial in absence of such registration. It also seeks to make the ethics committee responsible for reviewing reports on serious adverse events and recommending adequate compensation in accordance with the guidelines (discussed below). It reiterates composition of the ethics committee and specifies the records and documents to be maintained by the ethics committees.

The third step, namely the 'Guidelines for Determining Quantum of Financial Compensation to be paid in case of Clinical Trial Related Injury or Death', are issued by the CDSCO on August 3, 2012. As the name suggests, the guidelines seek to provide a mechanism for calculation of compensation in cases of injury or death related to clinical trials, based on the parameters of age and income of the subjects, seriousness and severity of the disease and extent of permanent disability (in cases of injury).

The guidelines note that in terms of the GCP Guidelines, any research subject who suffers physical injury, as a result of his participation in clinical trials, is entitled to financial or other assistance to compensate equitably for any temporary or permanent impairment or disability. In case of death, the dependents of the subject are entitled to material compensation. The GCP Guidelines, however, do not provide for the procedure for payment of compensation and criteria for determining the amount of financial/material compensation to be paid in the cases of injury or death. The guidelines seek to fill this void once finalized and enforced.

The notifications and guidelines are sequel to the notification on clinical trial compensation published earlier by the MoH&FW on November 18, 2011 invit-

ing suggestions and objections from the public. Our submissions to the earlier notification of the MoH&FW dated December 30, 2011 are available here.

By: Alishan Naqvee, Partner (anaqvee@lexcounsel.in) and Dhruv Manchanda, Associate (dmanchanda@lexcounsel.in)